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User Manual

CARDIALYS

37-055 V3.0

Date of the first placing on the market of the product: 04/05/2010

CE 0459

PARSYS TELEMEDECINE

10/15/2015 Version

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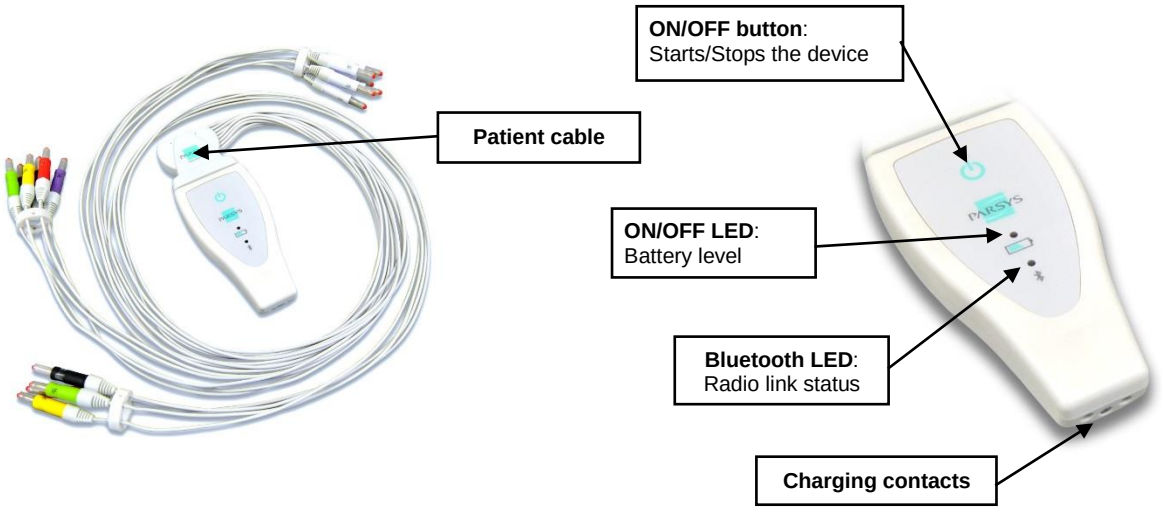
We thank you for having chosen PARSYS Telemedicine equipment. We hope that it will bring you full satisfaction in your daily electrocardiography practice.

1 Kit contents

1.1 Components and accessories of the kit



Firstly, please **check the components and accessories** of your **Cardialys** Kit (Ref: 200-001/2/3/4).

- 12 derivations with clips (Ref: 200-003)
- 12 derivations with bananas (Ref: 200-001)
- 18 derivations with clips (Ref: 200-004)
- 18 derivations with bananas (Ref: 200-002)

It must contain the following items:

- 1 Differentiator box Cardialys — Ref: 25-005
- 1 Bluetooth USB adapter — Ref: 36-002
- 1 Patient cable* (according to option):
  - ✓ 12-lead with clips 4mm — Ref: 23-023 A
  - ✓ 12-lead with bananas — Ref: 23-023 B
  - ✓ 12 to 18-lead clips 4mm — Ref: 23-024 A
  - ✓ 12 to 18-lead bananas — Ref: 23-024 B
- 1 Charging base DC 5V/1,1A — Ref: 25-019
- 1 Medical (EN 60601) 5V power supply and cord — Ref: 16-001
- 1 Water spray — Ref: 36-006
- 1 Reset black cord (for device reset) — Ref: 23-051
- 1 Carry case — Ref: 34-003
- 1 User Manual Cardialys - EN — Ref: 37-055
- 1 Warranty Card - EN — Ref: 37-003

If any of the items is missing, please contact us at the address given in the manual.

1.2 List and explanation of the meaning of the symbols used

Warning: consult attached documents

Please read the notice

BF type applied part

Do not dispose of in the bin but through the appropriate recycling channels.

Non-ionizing radiation

Product manufactured by PARSYS Telemedecine

Device climatic range of use or storage

S/N Serial number

CE Medical device European compliance

1.3 Warnings

PARSYS Telemedicine draws the attention of the user on the following points regarding:

⚠ The device **must not be used simultaneously** with an electric surgery tool.

⚠ The device **is not intended** for cardiac direct use (reserved to CF class devices).

⚠ The ECG capture **must not be performed** when the device is charging on its charger.

⚠ When the ECG is capturing, electrodes unplugged on the patient **must not come into contact** with the ground or other exposed metal parts.

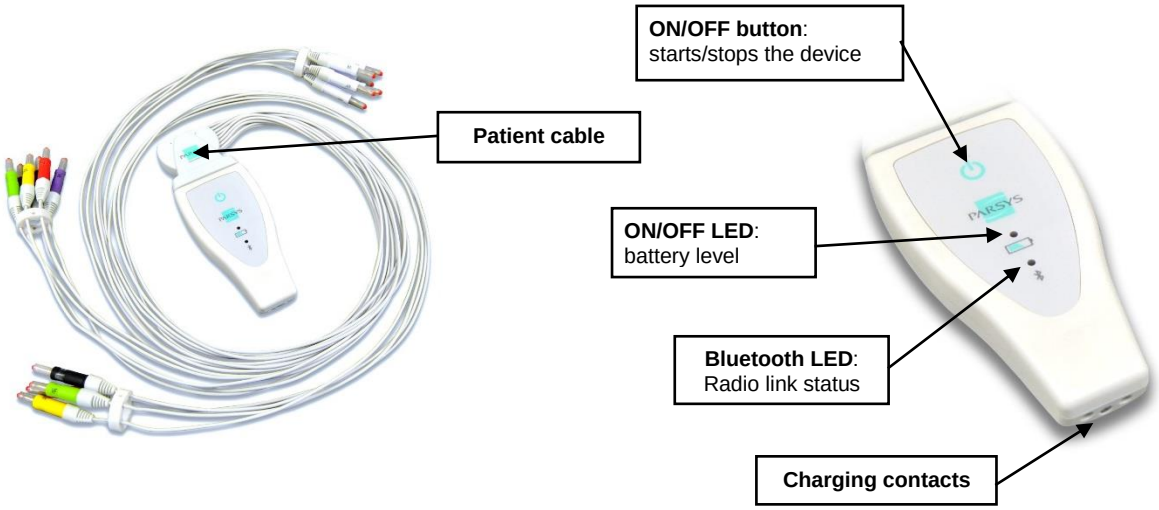
⚠ When the ECG is capturing, the device's differentiator box **must be in contact** with the patient.

⚠ In case of a simultaneous use of the device and another, **it should take care** that the sum of the patient leakage currents to the ground doesn't exceed safety limits.

⚠ In case of a simultaneous use of the device with a defibrillator, **do not place** the defibrillator's electrodes into contact with the device's electrodes.

2 Equipment description

2.1 Overview



Cardialys is a portable electrocardiograph with the following characteristics:

- capture by wired electrodes,
- possibility of acquiring a 12 or 18-lead ECG on the same number of tracings,
- each lead is recorded simultaneously over a 12-second period or an adjustable period on request during use in autonomous mode,
- transmission of the signal to a PC via Bluetooth,
- IIa class ECG device for temporary use.

2.2 Functional description

2.2.1 Use in Direct mode

Cardialys can be set to automatically capture and transmit an ECG trace to a PC with the supplied software Telecardialys configured in "**Direct**" mode: direct capture of an ECG trace, without preview.

2.2.2 Use in Preview mode

Cardialys can be set to automatically capture and transmit an ECG trace to a PC with the supplied software Telecardialys configured in "**Preview**" mode: preview of the ECG trace, then capture of an ECG trace.

2.2.3 Starting / Stopping the device

The device is switched on by pressing the button on the front of the case for a few seconds until the **ON/OFF** LED goes out.

ON/OFF button

Turn off in Direct mode:
The Cardialys automatically turns off after transmission of the ECG trace to the PC.

Turn off in Preview mode:
Turn off the Cardialys by holding down the **ON/OFF** button until the LED stops flashing. The shutdown sequence is automatic, you can release the button.

2.3 Patient cable

The patient cable connects to Cardialys using the DB25 plug at the top of the instrument. The cable comes with 2 end fittings and in 2 types according to the number of leads to be acquired:

- with banana plug, in 12 or 18-lead model.
- with 4 mm clip for adhesive electrodes, in 12 or 18-lead model.

The selection must be made at the time of purchase of the instrument.

The operating PC software nevertheless makes it possible to select just 12 leads when using an 18-lead cable.

2.4 Charging system

2.4.1 Charger use

Cardialys is equipped with a separate power supply provided by a rechargeable Lithium/Polymer battery, allowing approximately 50 traces per charge. This battery is recharged using the charger, via 2 metal contacts integrated into the rear of the machine unit.

The Cardialys charger is a horizontal or vertical mounting model specially designed for use on carts, cases or vehicles, potentially in confined spaces.

2.4.2 Starting the charger

The charger charges the machine completely in approximately **2.5 hours** using a 220V/50Hz source, via the mains adapter supplied.

The charger requires a 220V / 50Hz power source. So just plug it into the mains to power it and therefore proceed with charging the Cardialys ECG battery.

The Cardialys charger does not have a switch. Charging the device switches on when the charger receives the necessary power from the power cable connected to the mains.

⚠ **We recommend you not to modify the Cardialys charger as permanent damage not covered by the warranty of the device.**

2.4.3 Description of indicators

The charge light indicator is:

- **OFF** while Cardialys is **not correctly inserted** or missing from the slot,
- **RED** as Cardialys is **charging,**
- **GREEN** when Cardialys is **charged**.

2.4.4 Cardialys charging procedure

The Cardialys ECG must be positioned in the load position.

⚠ **Warning: The Cardialys box WITH its Patient cable (fixed together by clamping screws) must be inserted in the charger to ensure good contact with the charging metal contacts.**

The charger ensures full recharging of Cardialys in about **2.5 hours**.

⚠ **WARNING: THE DEVICE MUST NOT BE USED WHILE IT IS CHARGING.**

2.4.5 When should I charge Cardialys?

The Cardialys charge level is indicated by the ON/OFF LED on the case of the device.

Cardialys' battery life is short and you should ensure you pay close attention to the color code below:

Battery ON/OFF LED:
- **GREEN**: sufficient battery level
- **ORANGE**: insufficient battery level
- **RED**: discharged battery

WE RECOMMEND CHARGING THE DEVICE AS SOON AS THE INDICATOR BECOMES "ORANGE" AND BEFORE THE BATTERY BECOMES FULLY DISCHARGED.

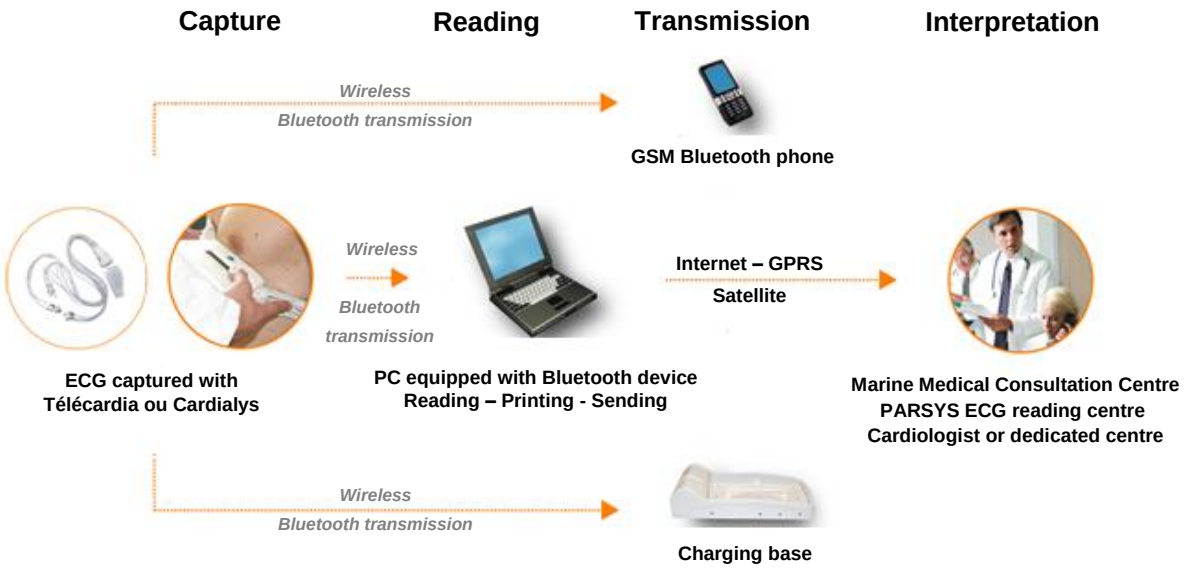
2.5 ECG reading

Viewing and/or transmission of the trace on a PC

Following capture, the data is sent to the PC automatically via the Bluetooth radio link which has a free field range of approximately 100 meters. This requires the presence of a Bluetooth USB adapter, supplied in the kit, connected to the PC used to operate Cardialys.

On the operating PC, the Telecardialys software (See the User Manual Telecardialys Software - 37-063 V1.0) is used to:

- dialogue with the equipment via Bluetooth,
- display the captured ECGs,
- print the ECGs in several report modes,
- send the captured ECGs by e-mail,
- archive and view the captured ECGs.



3 Installation of Telecardialys PC Software

See the User Manual Telecardialys Software - 37-063 V1.0

4 Bluetooth pairing procedure of the Cardialys to a PC

Windows XP	Windows Vista		Windows 7 and above	
External adapter	External adapter	Internal module	External adapter	Internal module
Installation CD §xxx	Installation CD §xxx	Nothing to do	Insert adapter + Internet	Nothing to do

The pairing procedure of the Cardialys ECG with a PC running Windows 7 and above is specific: it is essential to follow the appropriate procedure for the operating system of your PC.

4.1 Windows XP Operating System

Pairing of Cardialys with a Windows XP PC

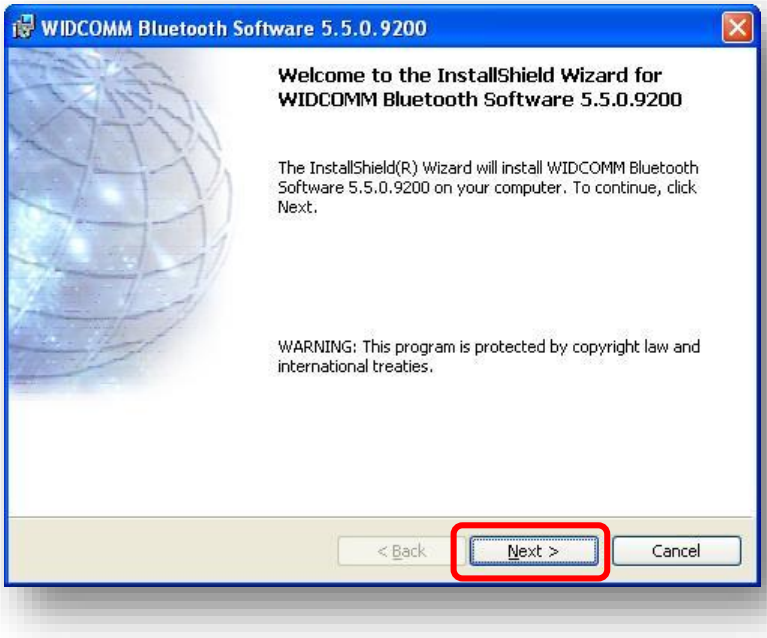
The Bluetooth USB adapter is pre-associated by us with your Cardialys.
Use the following procedure in the following cases:

a. **you change your Bluetooth USB adapter,**
b. **you do not use the supplied adapter to the benefit of an internal Bluetooth module,**
c. **you use another Cardialys with the same adapter (potential After-Sales return).**

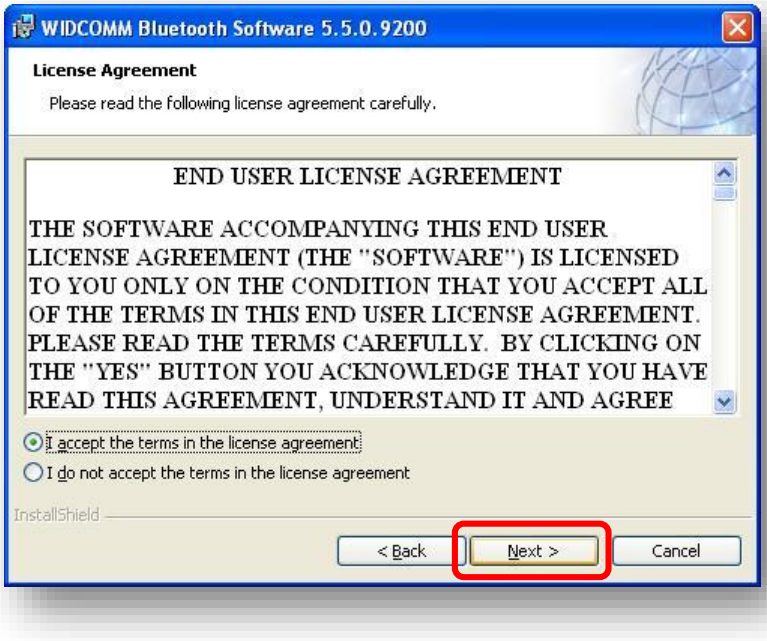
Insert the USB Bluetooth adapter into an USB port on the PC, then run the installation CD.

If the CD does not run automatically, please run it manually in Windows Explorer.

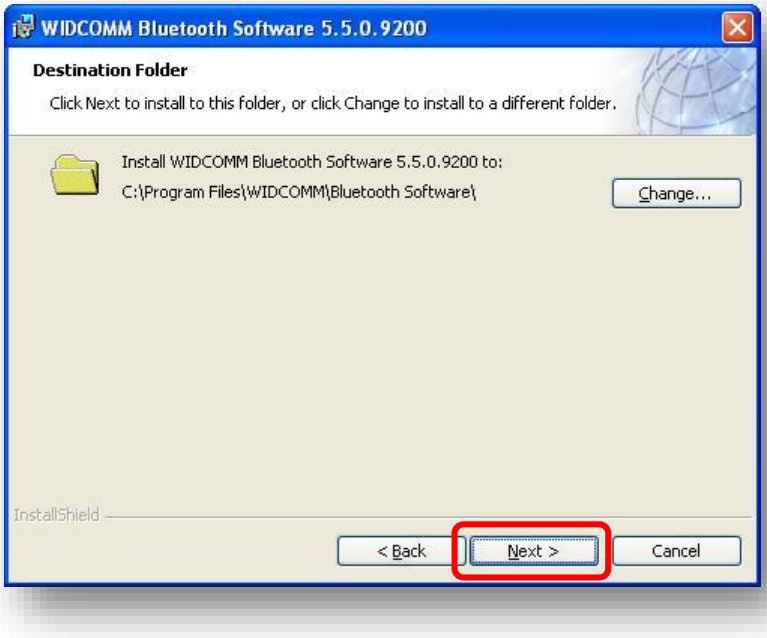
Do nothing until this window appears. Click on "**Install Bluetooth© Device**".


WIDCOMM Bluetooth Software 5.5.0.9200
Welcome to the InstallShield Wizard for WIDCOMM Bluetooth Software 5.5.0.9200
The InstallShield(R) Wizard will install WIDCOMM Bluetooth Software 5.5.0.9200 on your computer. To continue, click Next.
WARNING: This program is protected by copyright law and international treaties.
< Back
Next >
Cancel

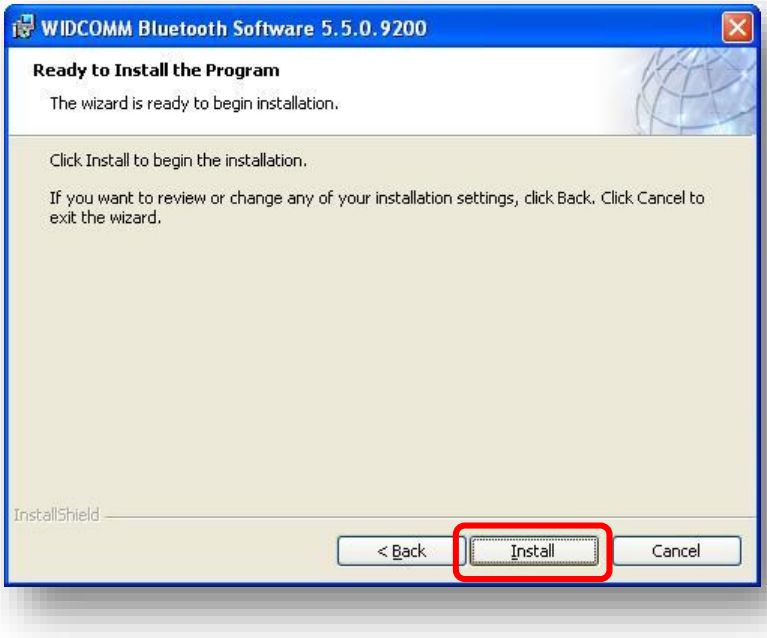
Click on "**Next >**".


WIDCOMM Bluetooth Software 5.5.0.9200
License Agreement
Please read the following license agreement carefully.
END USER LICENSE AGREEMENT
THE SOFTWARE ACCOMPANYING THIS END USER LICENSE AGREEMENT (THE "SOFTWARE") IS LICENSED TO YOU ONLY ON THE CONDITION THAT YOU ACCEPT ALL OF THE TERMS IN THIS END USER LICENSE AGREEMENT. PLEASE READ THE TERMS CAREFULLY. BY CLICKING ON THE "YES" BUTTON YOU ACKNOWLEDGE THAT YOU HAVE READ THIS AGREEMENT, UNDERSTAND IT AND AGREE
I accept the terms in the license agreement
I do not accept the terms in the license agreement
InstallShield
< Back
Next >
Cancel

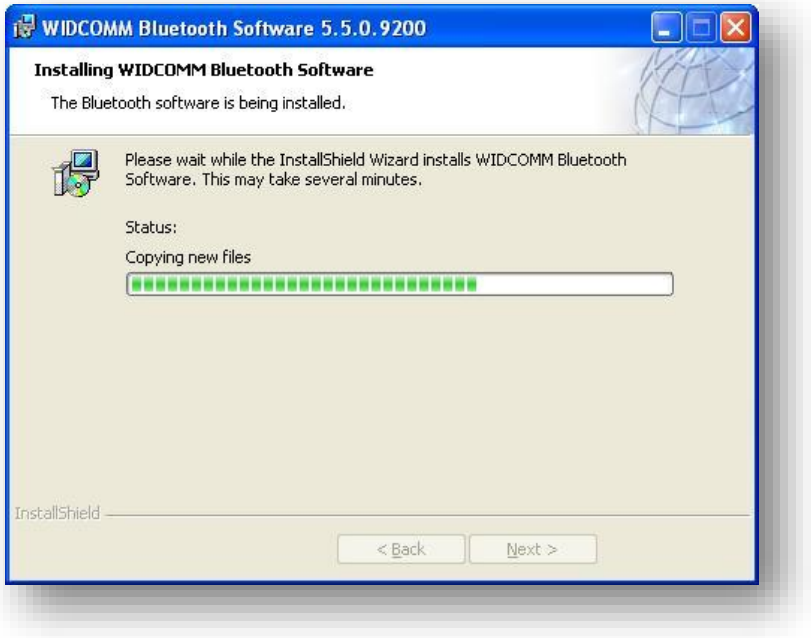
Accept the agreement, then click on "**Next >**".


WIDCOMM Bluetooth Software 5.5.0.9200
Destination Folder
Click Next to install to this folder, or click Change to install to a different folder.
Install WIDCOMM Bluetooth Software 5.5.0.9200 to:
C:\Program Files\WIDCOMM\Bluetooth Software\
Change...
InstallShield
< Back
Next >
Cancel

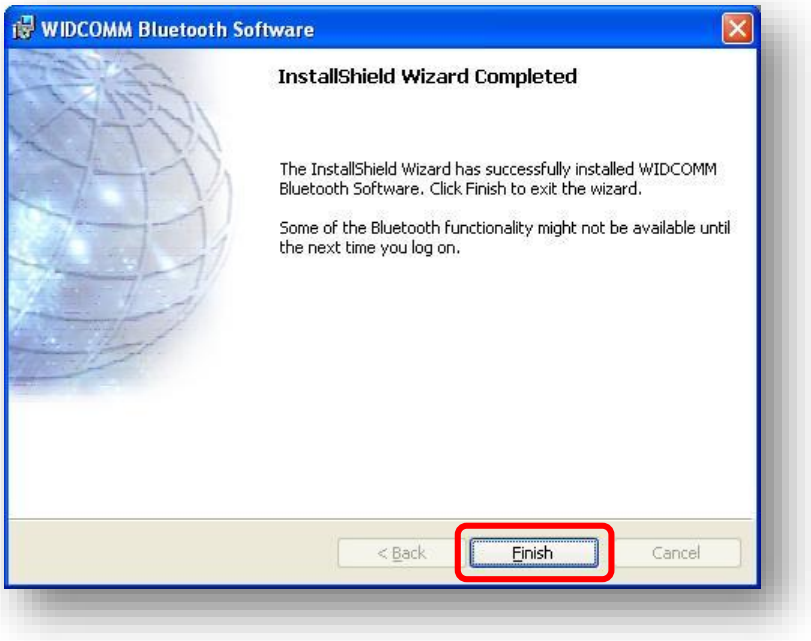
Click on "**Next >**".


WIDCOMM Bluetooth Software 5.5.0.9200
Ready to Install the Program
The wizard is ready to begin installation.
Click Install to begin the installation.
If you want to review or change any of your installation settings, click Back. Click Cancel to exit the wizard.
InstallShield
< Back
Install
Cancel

Click on "**Install**".

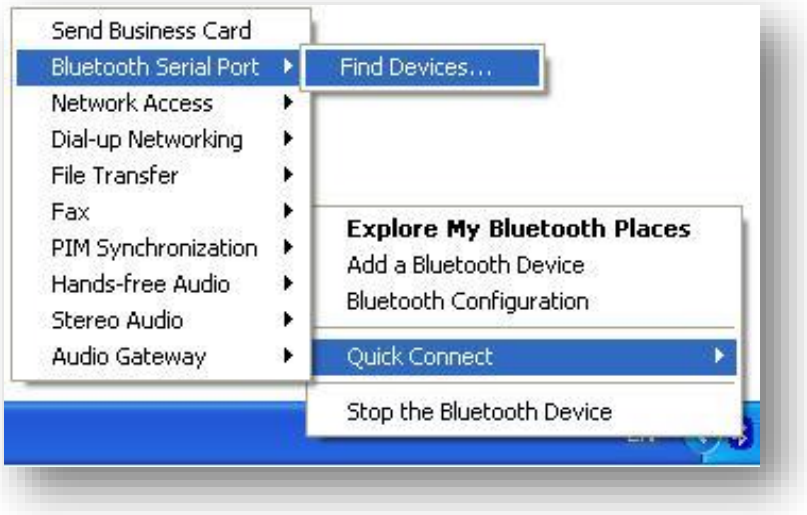

WIDCOMM Bluetooth Software 5.5.0.9200
Installing WIDCOMM Bluetooth Software
The Bluetooth software is being installed.
Please wait while the InstallShield Wizard installs WIDCOMM Bluetooth Software. This may take several minutes.
Status:
Copying new files
InstallShield
< Back
Next >

Wait until the installation completes.


WIDCOMM Bluetooth Software
InstallShield Wizard Completed
The InstallShield Wizard has successfully installed WIDCOMM Bluetooth Software. Click Finish to exit the wizard.
Some of the Bluetooth functionality might not be available until the next time you log on.
< Back
Finish
Cancel

Click on "**Finish**".

Make a “right click” on the Bluetooth icon at the bottom right of the screen.



Click on “**Quick Connect**”,
then, on “**Bluetooth Serial Port**”,
then, on “**Find Devices…**”.

Bluetooth Device Selection
Select a device
Remote devices must be in Discoverable mode for this computer to find them.
For assistance in making a remote device discoverable, refer to the remote device's documentation.
ADANTENY-7
ADANTENY-F...
B07030334
B07050006
B07050017
B07050132
B07050254
CHABIOT
OBDI-VALIDA
PC-SER
Search Again
Show all devices
If the device you are looking for is not in the list, verify that the device has power and is operational. On some devices, you must press the Connect button to make the device discoverable.
Next >
Cancel

Open the drop down menu:
"**Show devices**" and select
"Show all devices".

Turn back the Cardialys box

Note the device ID (S/N) on its label:
Number starting with D

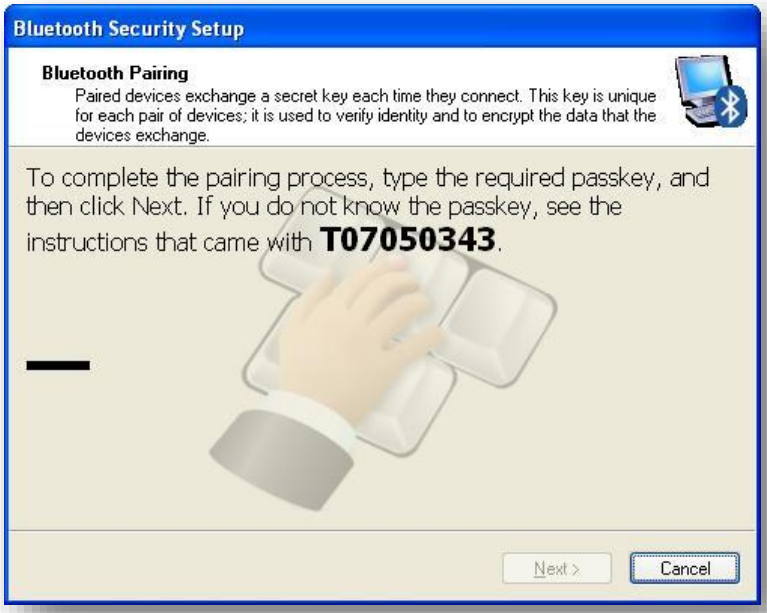
Make the connection.

Hold down the **ON/OFF** button until the display of its ID on the screen.

Bluetooth Device Selection
Select a device
Remote devices must be in Discoverable mode for this computer to find them.
For assistance in making a remote device discoverable, refer to the remote device's documentation.
B07050132
B07050254
CHARIOT
ORDI-VALIDA...
PC-SEB
Station test
T07050343
Search Again
Show all devices
If the device you are looking for is not in the list, verify that the device has power and is operational. On some devices, you must press the Connect button to make the device discoverable.
Next >
Cancel

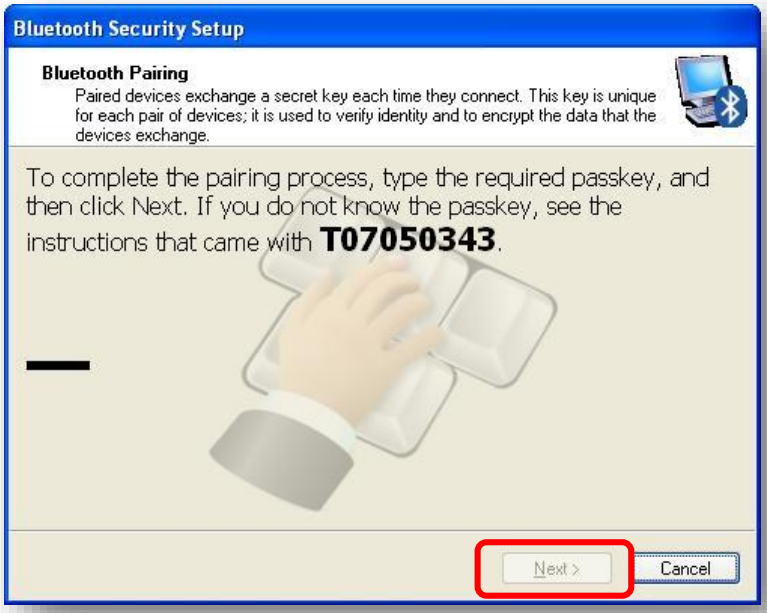
Select the device.

In the list, select your Cardialys and click on “**Next >**”.
If necessary, click on “**Search Again**”.


Bluetooth Security Setup
Bluetooth Pairing
Paired devices exchange a secret key each time they connect. This key is unique for each pair of devices; it is used to verify identity and to encrypt the data that the devices exchange.
To complete the pairing process, type the required passkey, and then click Next. If you do not know the passkey, see the instructions that came with T07050343.
Next >
Cancel

Pairing.

Pairing starts with Cardialys.


Bluetooth Security Setup
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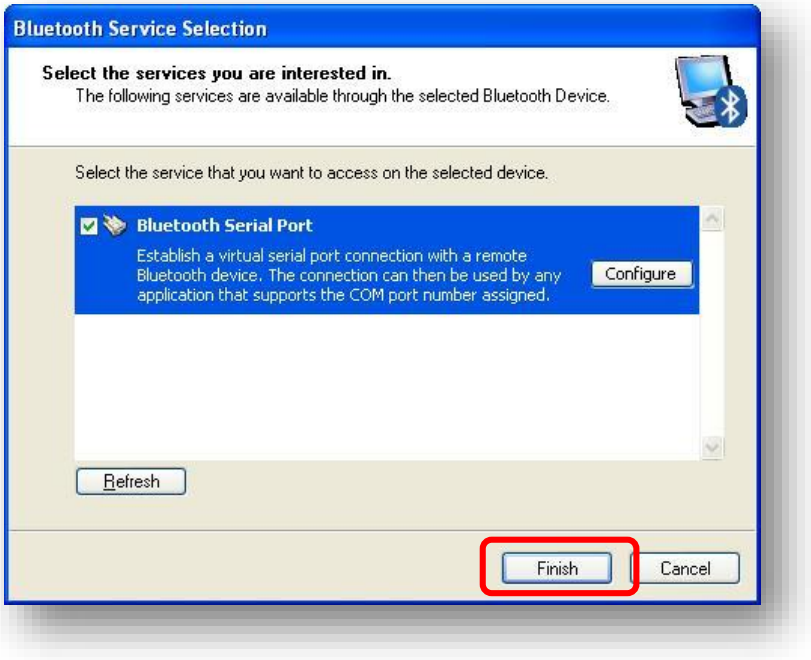
To complete the pairing process, type the required passkey, and then click Next. If you do not know the passkey, see the instructions that came with T07050343.
Next >
Cancel

Enter the pairing passkey:

The installer asks for a **passkey**:
Type the code: **02101124** and click on "**Next >**".


Bluetooth Service Selection
Select the services you are interested in.
The following services are available through the selected Bluetooth Device.
Select the service that you want to access on the selected device.
Bluetooth Serial Port
Establish a virtual serial port connection with a remote Bluetooth device. The connection can then be used by any application that supports the COM port number assigned.
Configure
Refresh
Finish
Cancel

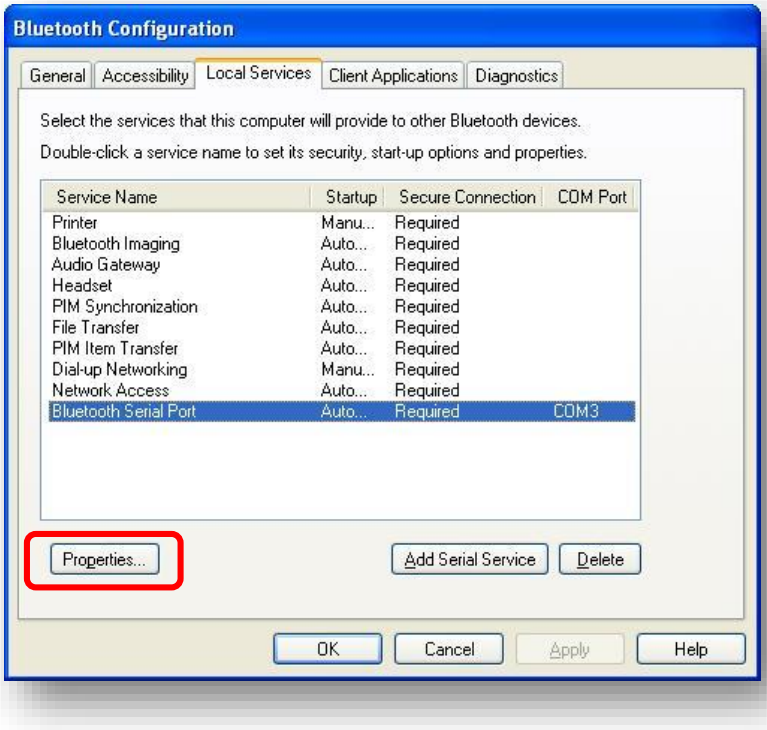
Click on “**Finish**”.

My Bluetooth Places
Shortcuts for the selected services have been created on the My Bluetooth Places screen of Windows Explorer.
Do not display this message again
OK

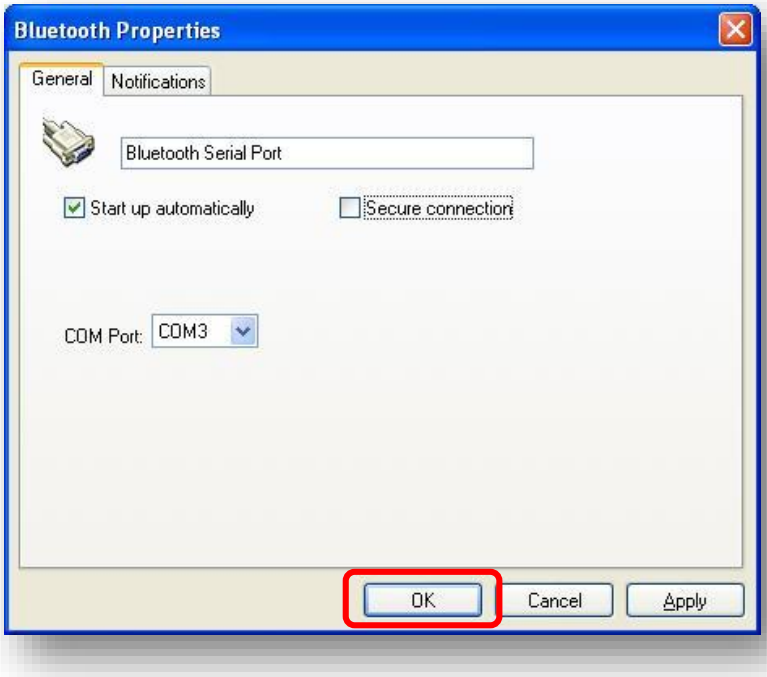
Create shortcuts.

Click on “**Do not display this message again**”, then on “**OK**”.

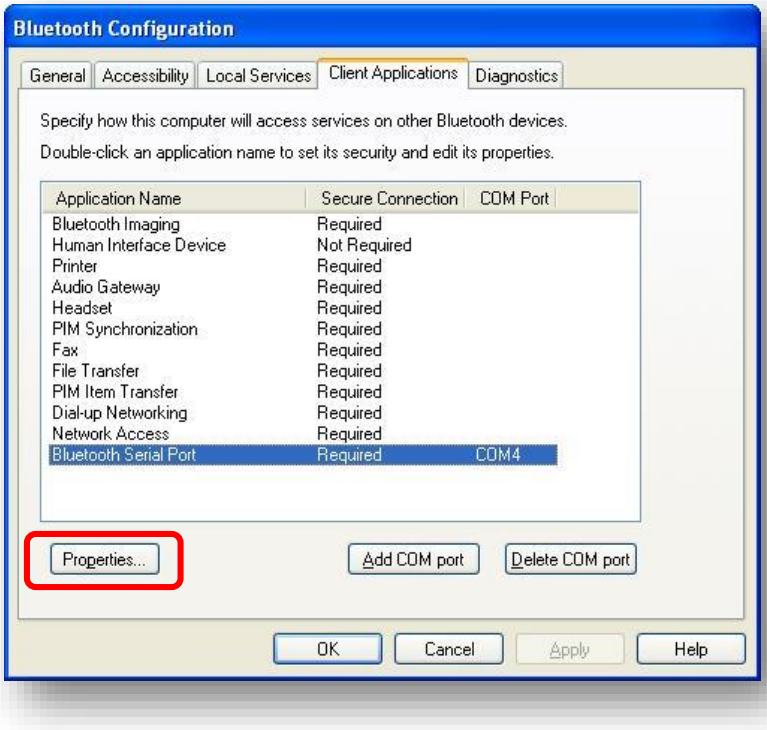
To finalize the installation of the Bluetooth device,
make a "right click" on the Bluetooth icon in the bottom right of the screen.
Then, click on “**Bluetooth Configuration**”.



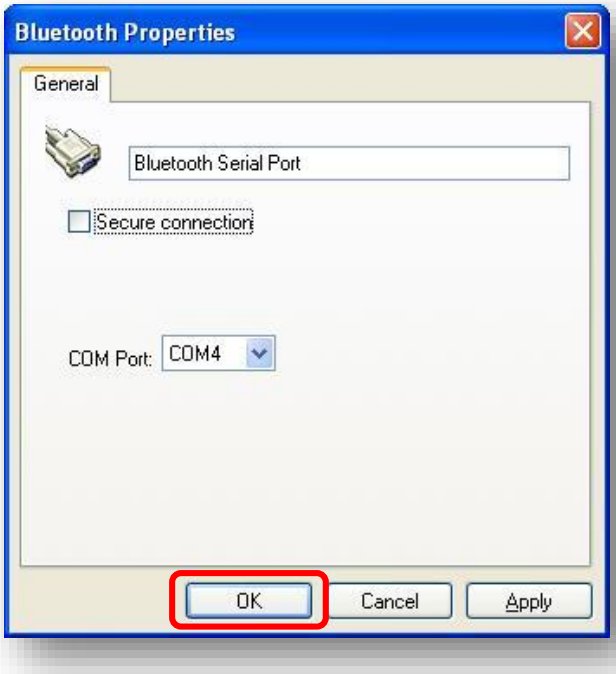
Go to the "**Local Services**" tab.
Click on "**Bluetooth Serial Port**".
Then, click on "**Properties…**".



Check "**Start up** automatically" and uncheck "**Secure connection**".
Click on "**Apply**", then on "**OK**".



Go to the "**Client Applications**" tab.
Click on "**Bluetooth Serial Port**".
Then, click on "**Properties…**".



Uncheck "**Secure connection**".

Click on "**Apply**", then on "**OK**".

4.2 Windows 7 Operating System

4.2.1 Requirements

4.2.1.1 Check if the PC (fixed, portable PC, ultraportable, Tablet PC...) to pair with the ECG includes a preinstalled Bluetooth internal module.

Note: In the case of a fixed PC, there is a good chance that there is no internal module; but, mobile computers often have a preinstalled Bluetooth internal module.

4.2.1.2 If no internal module is preinstalled, use the Bluetooth USB adapter supplied with your kit.

- It is fundamental that your computer **has an active Internet connection**.
- Just plug your Bluetooth USB adapter on a USB port, driver installation is automatic via the Internet.

In this case, your computer must be connected to the Internet to install the Bluetooth USB adapter (driver updating).

4.2.1.3 If your computer is equipped with a preinstalled Bluetooth internal module, check the origin of its stack.

Microsoft / WidComm stack: Pairing is automatic between Cardialys and the computer, you have no other manipulation to perform

Another provider stack: We recommend you to communicate the name of the stack provider to the PARSYS Telemedicine After-Sales Service before any installation.

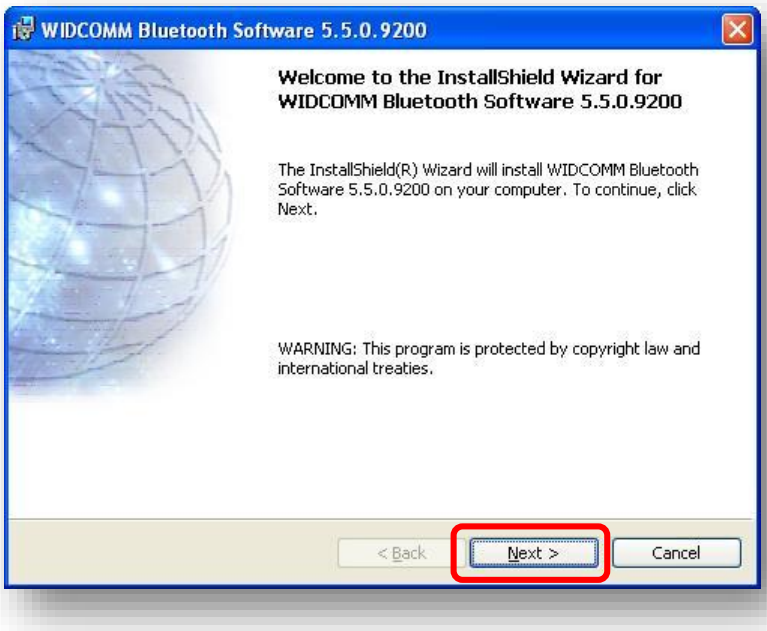
In the latter case, we recommend not to try the installation before obtaining confirmation procedure by the PARSYS Telemedicine After-Sales Service.

4.2.2 Pairing of Cardialys with a Windows 7 PC

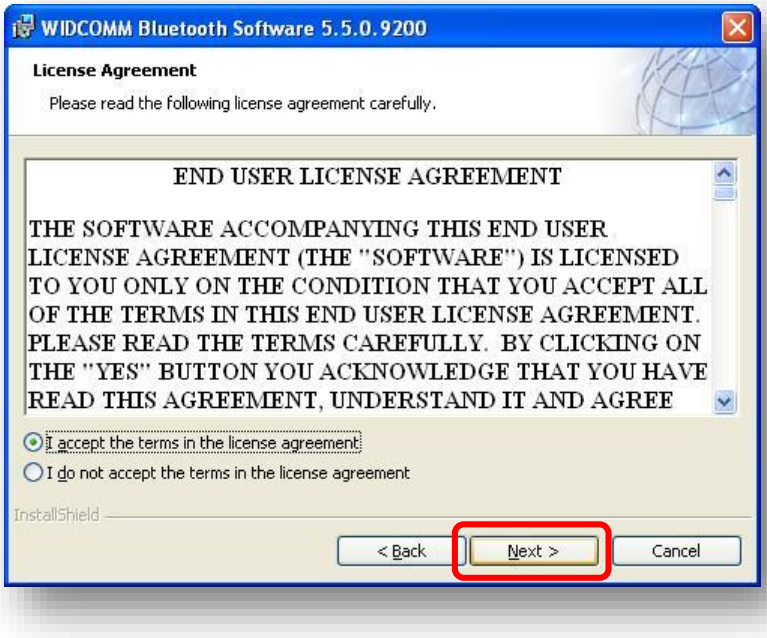
Insert the USB Bluetooth adapter into an USB port on the PC, then run the installation CD.

If the CD does not run automatically, please run it manually in Windows Explorer.

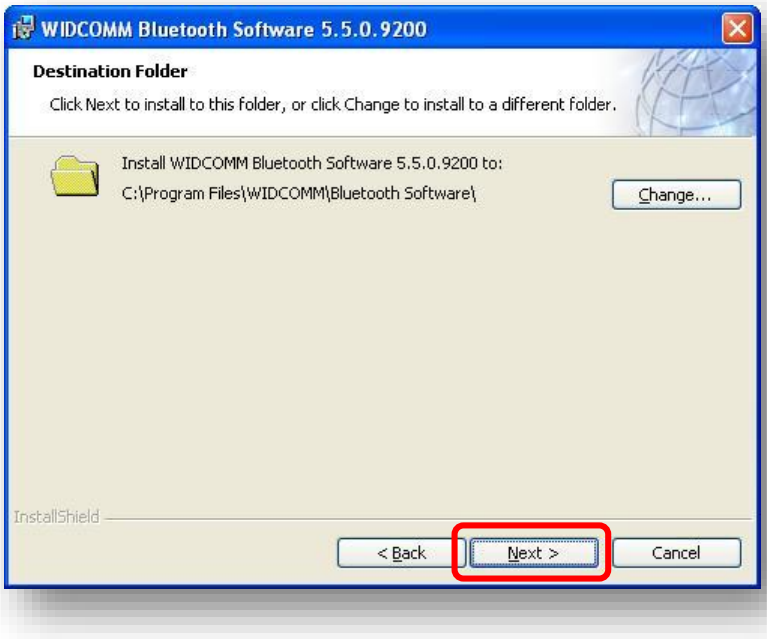
Do nothing until this window appears. Click on "**Install Bluetooth© Device**".


WIDCOMM Bluetooth Software 5.5.0.9200
Welcome to the InstallShield Wizard for WIDCOMM Bluetooth Software 5.5.0.9200
The InstallShield(R) Wizard will install WIDCOMM Bluetooth Software 5.5.0.9200 on your computer. To continue, click Next.
WARNING: This program is protected by copyright law and international treaties.
< Back
Next >
Cancel

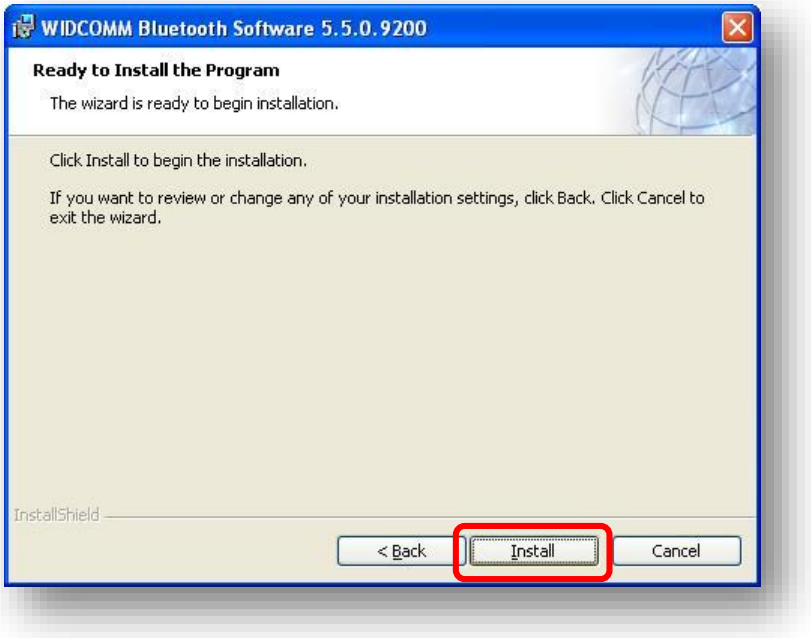
Click on "**Next >**".


WIDCOMM Bluetooth Software 5.5.0.9200
License Agreement
Please read the following license agreement carefully.
END USER LICENSE AGREEMENT
THE SOFTWARE ACCOMPANYING THIS END USER LICENSE AGREEMENT (THE "SOFTWARE") IS LICENSED TO YOU ONLY ON THE CONDITION THAT YOU ACCEPT ALL OF THE TERMS IN THIS END USER LICENSE AGREEMENT. PLEASE READ THE TERMS CAREFULLY. BY CLICKING ON THE "YES" BUTTON YOU ACKNOWLEDGE THAT YOU HAVE READ THIS AGREEMENT, UNDERSTAND IT AND AGREE
I accept the terms in the license agreement
I do not accept the terms in the license agreement
InstallShield
< Back
Next >
Cancel

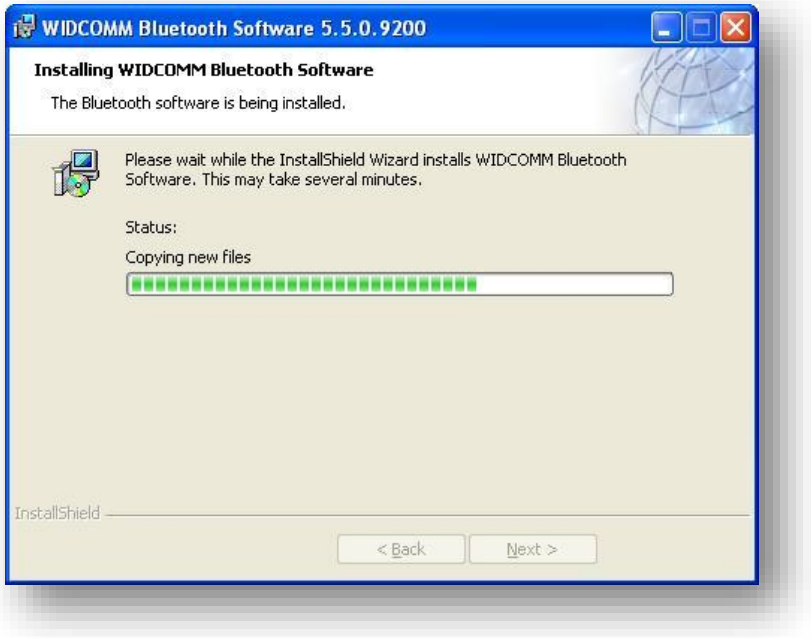
Accept the agreement, then click on "**Next >**".


WIDCOMM Bluetooth Software 5.5.0.9200
Destination Folder
Click Next to install to this folder, or click Change to install to a different folder.
Install WIDCOMM Bluetooth Software 5.5.0.9200 to:
C:\Program Files\WIDCOMM\Bluetooth Software\
Change...
InstallShield
< Back
Next >
Cancel

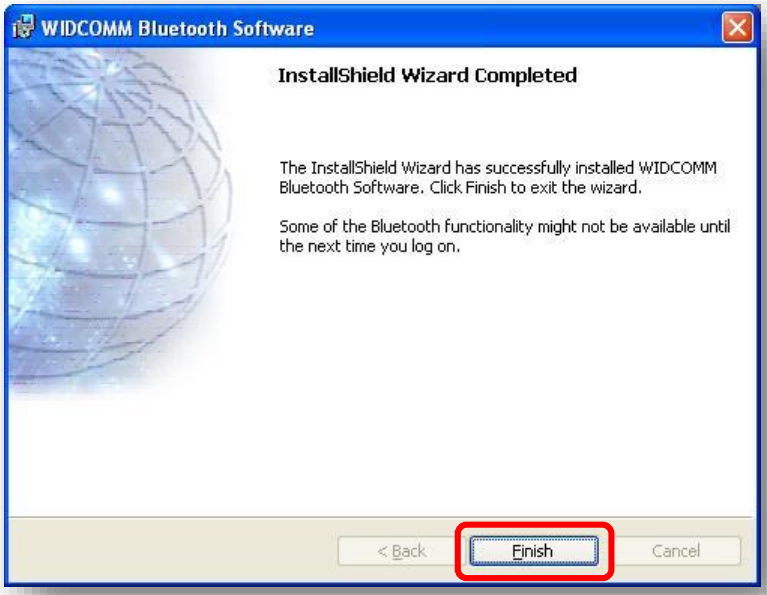
Click on "**Next >**".


WIDCOMM Bluetooth Software 5.5.0.9200
Ready to Install the Program
The wizard is ready to begin installation.
Click Install to begin the installation.
If you want to review or change any of your installation settings, click Back. Click Cancel to exit the wizard.
InstallShield
< Back
Install
Cancel

Click on "**Install**".

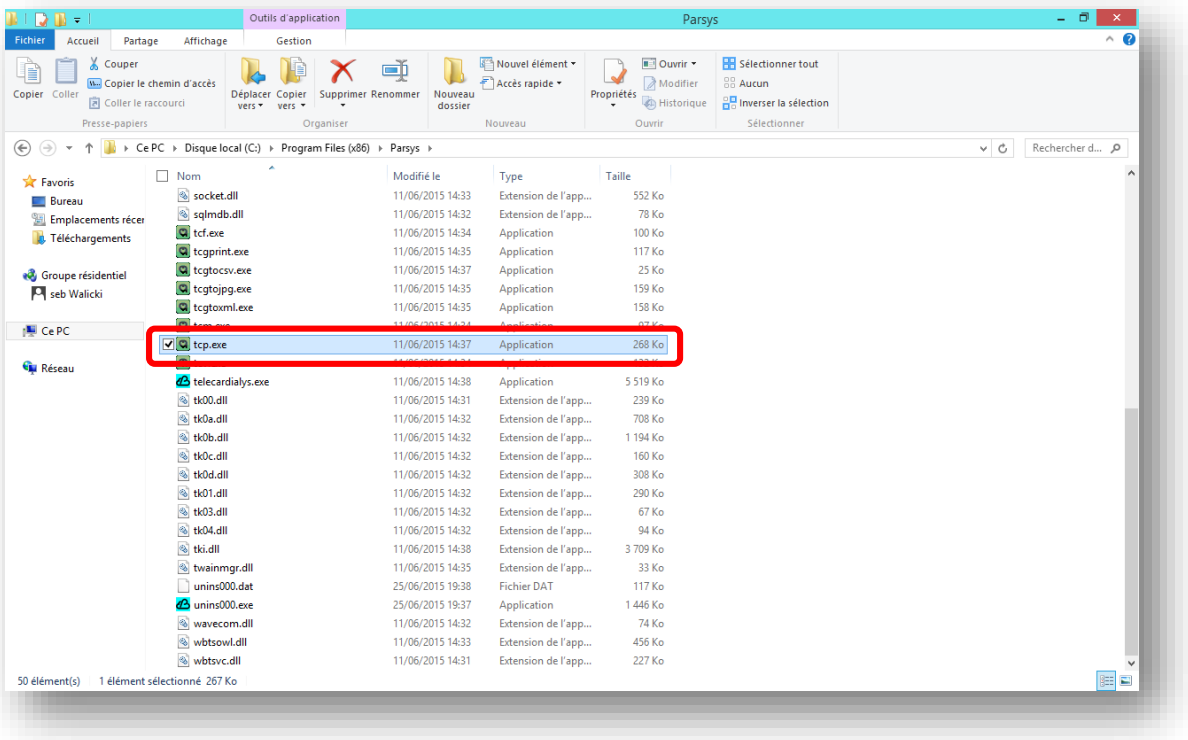

WIDCOMM Bluetooth Software 5.5.0.9200
Installing WIDCOMM Bluetooth Software
The Bluetooth software is being installed.
Please wait while the InstallShield Wizard installs WIDCOMM Bluetooth Software. This may take several minutes.
Status:
Copying new files
InstallShield
< Back
Next >

Wait until the installation completes.

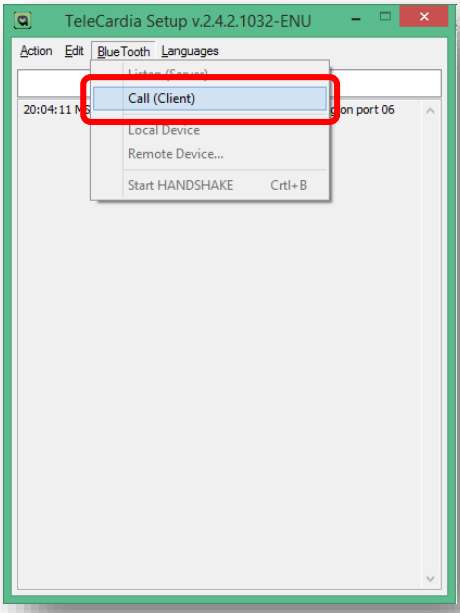

WIDCOMM Bluetooth Software
InstallShield Wizard Completed
The InstallShield Wizard has successfully installed WIDCOMM Bluetooth Software. Click Finish to exit the wizard.
Some of the Bluetooth functionality might not be available until the next time you log on.
< Back
Finish
Cancel

Click on "**Finish**".

Open the "**Program Files**" folder (32-bit processors) or "**Program Files (x86)**" (64-bit processors).



Then, open the "**Parsys**" folder and start the "**TCP.EXE**" software.



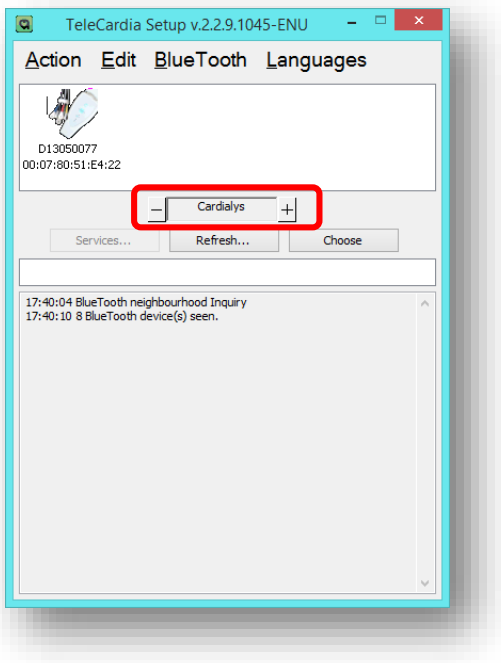
When the software is opened, set the device "**Call (Client)**" mode.

Turn back the Cardialys box

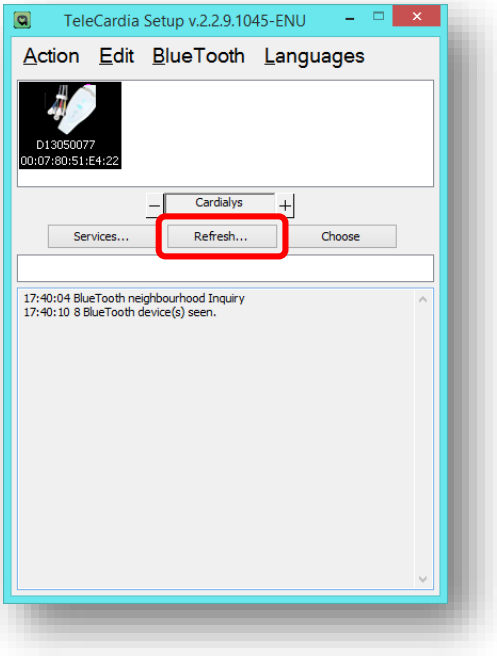
Note the device ID (S/N) on its label:
Number starting with D

Make the connection.

Hold down the **ON/OFF** button until the display of its ID on the screen.

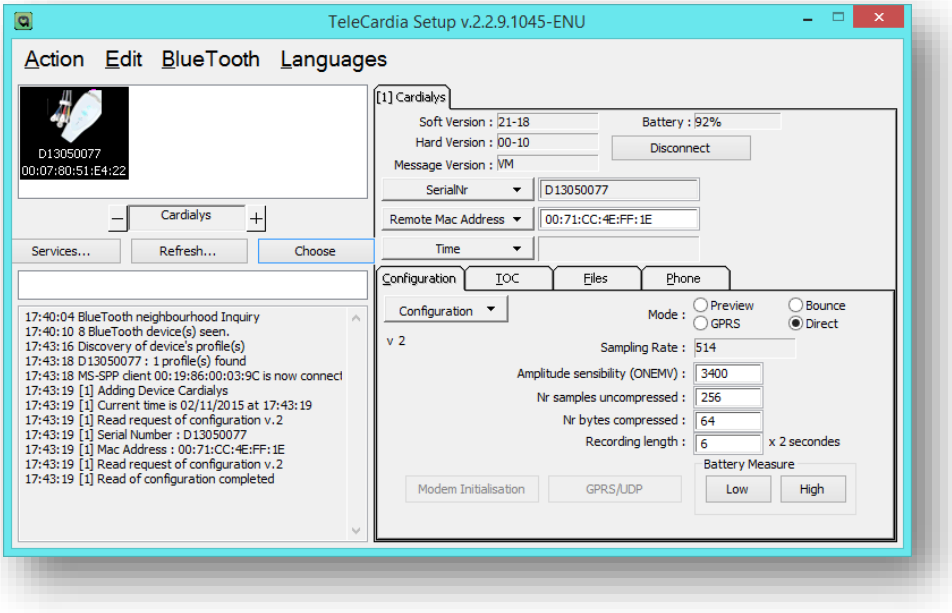


The different connectable Bluetooth devices are recognized by the system.
You can refine the search by type of equipment (Telecardia, Cardialys, etc.).

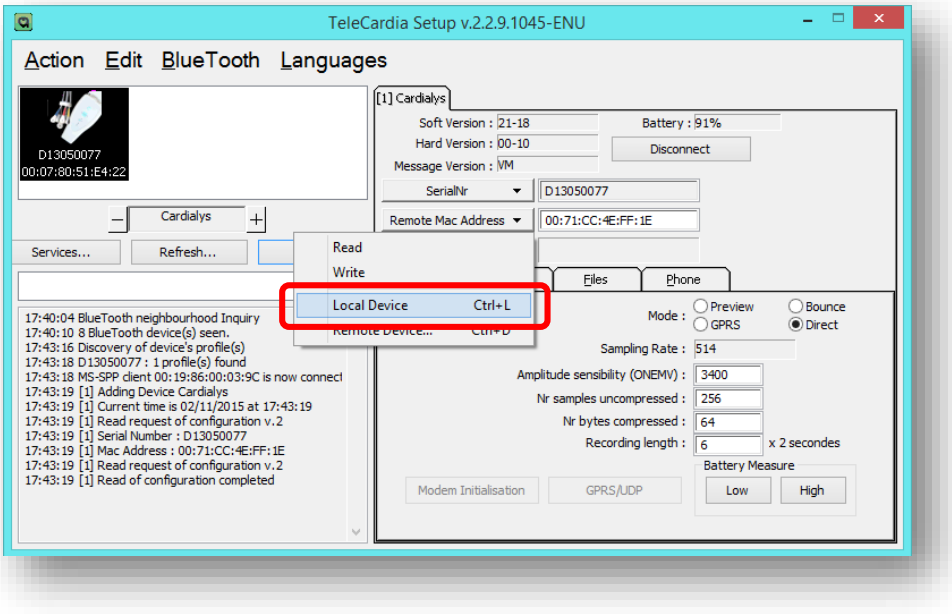


If the search is unsuccessful you can click on "**Refresh…**",
which will start a new search.

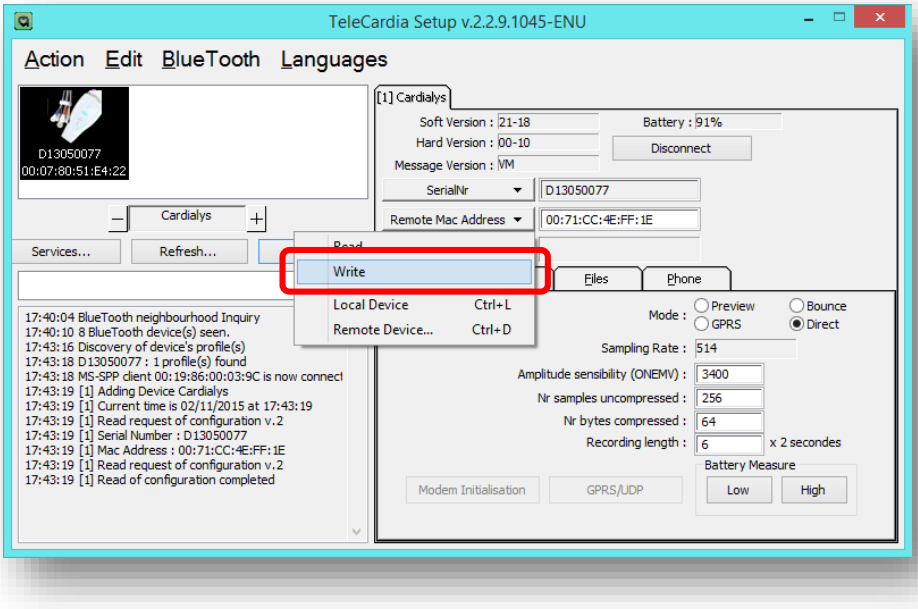
Once the desired device is visible, click its icon (although check the serial number).
Then, click on "**Choose**".



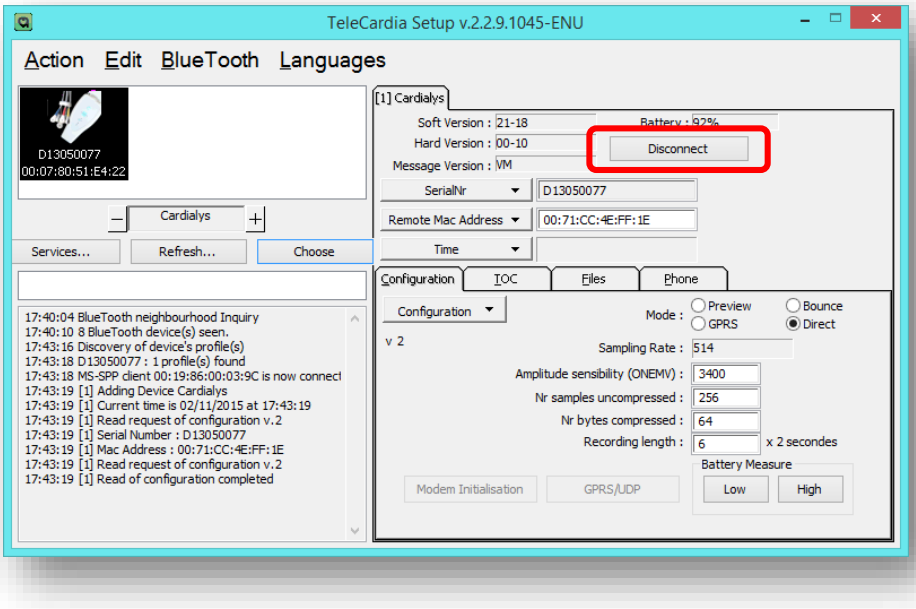
The interface window with the medical device is then visible.



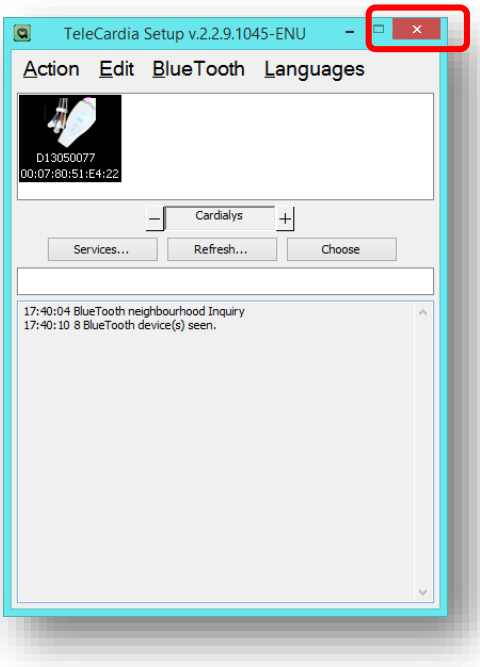
Click on "**Remote Mac Address**".
Then, click on "**Local Device**".
The PC MAC address will be registered.



Click on “**Remote Mac Address**”.
Then, click on “**Write**” to save the new MAC address.



Click on “**Disconnect**”.



Back to the start window of the "**TCP**" software.
Close the window to exit.

4.3 Windows 8 / 8.1 Operating System

4.3.1 Requirements

4.3.1.1 Check if the PC (fixed, portable PC, ultraportable, Tablet PC...) to pair with the ECG includes a preinstalled Bluetooth internal module.

Note: In the case of a fixed PC, there is a good chance that there is no internal module; but, mobile computers often have a preinstalled Bluetooth internal module.

4.3.1.2 If no internal module is preinstalled, use the Bluetooth USB adapter supplied with your kit.

- It is fundamental that your computer **has an active Internet connection**.
- Just plug your Bluetooth USB adapter on a USB port, driver installation is automatic via the Internet.

In this case, your computer must be connected to the Internet to install the Bluetooth USB adapter (driver updating).

4.3.1.3 If your computer is equipped with a preinstalled Bluetooth internal module, check the origin of its stack.

Microsoft / WidComm stack: Pairing is automatic between Cardialys and the computer, you have no other manipulation to perform

Another provider stack: We recommend you to communicate the name of the stack provider to the PARSYS Telemedicine After-Sales Service before any installation.

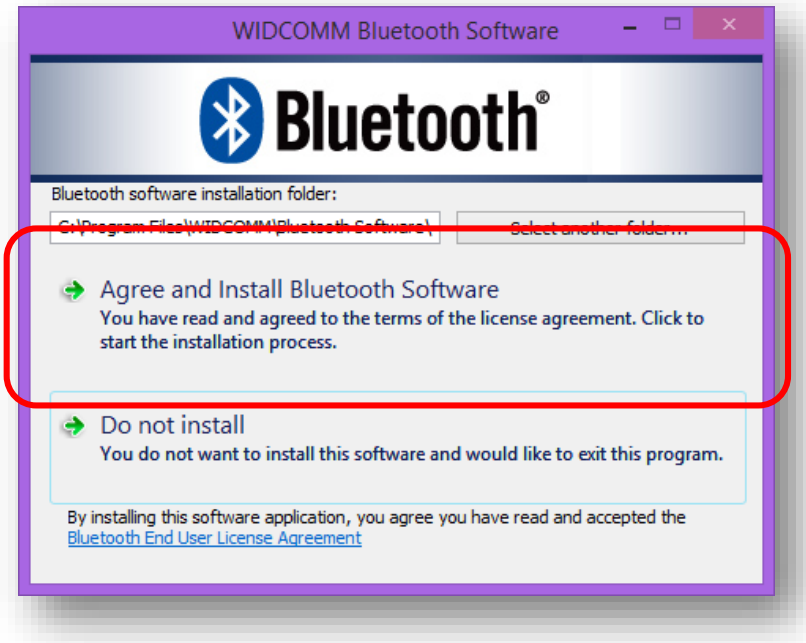
In the latter case, we recommend not to try the installation before obtaining confirmation procedure by the PARSYS Telemedicine After-Sales Service.

4.3.2 Pairing of Cardialys with a Windows 8 / 8.1 PC

Insert the USB Bluetooth adapter into an USB port on the PC, then run the installation CD.

If the CD does not run automatically, please run it manually in Windows Explorer.

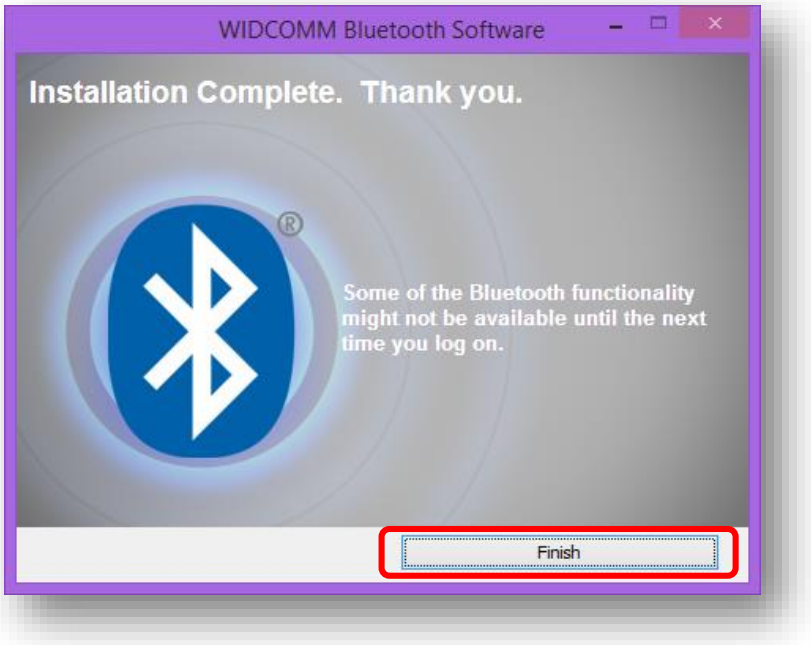
Do nothing until this window appears. Click on "**Install Bluetooth© Device**".


WIDCOMM Bluetooth Software
Bluetooth
Bluetooth software installation folder:
Agree and Install Bluetooth Software
You have read and agreed to the terms of the license agreement. Click to start the installation process.
Do not install
You do not want to install this software and would like to exit this program.
By installing this software application, you agree you have read and accepted the
Bluetooth End User License Agreement

Click on "**Agree and Install Bluetooth Software**".

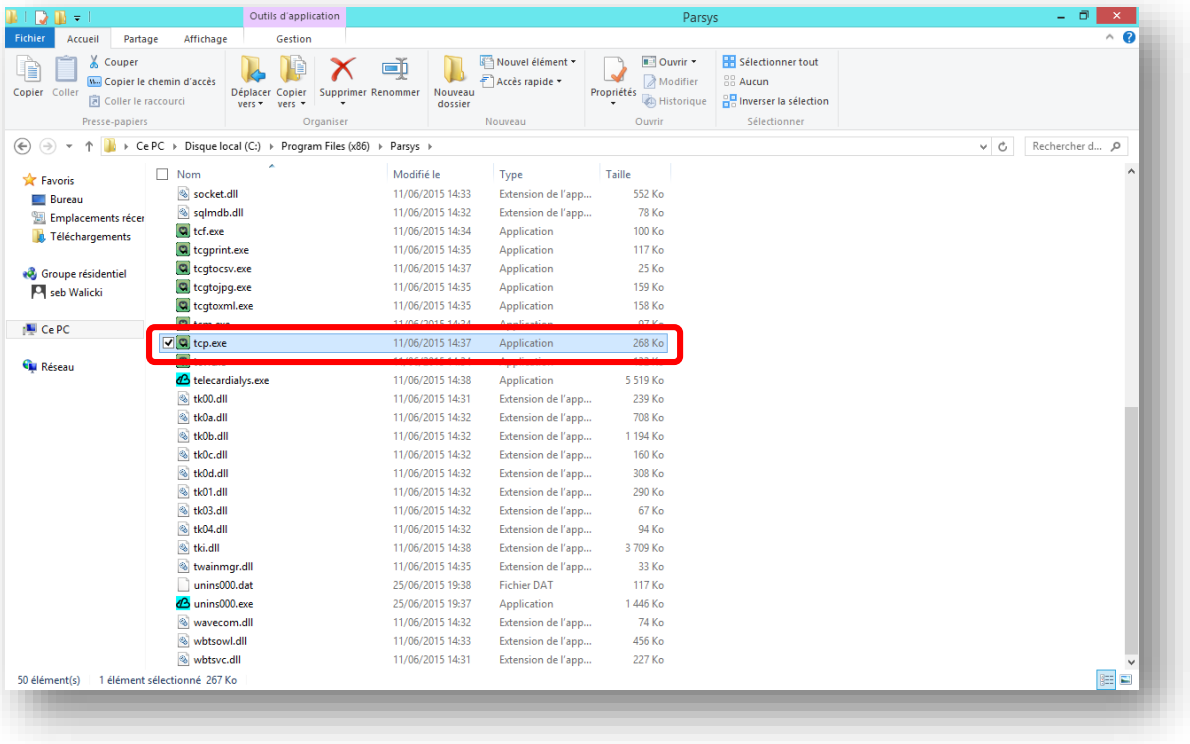
WIDCOMM Bluetooth Software
Hands-Free Audio
skype
Use Bluetooth hands-free devices to do calls over Skype™ or other VoIP applications.

Wait until the installation completes.

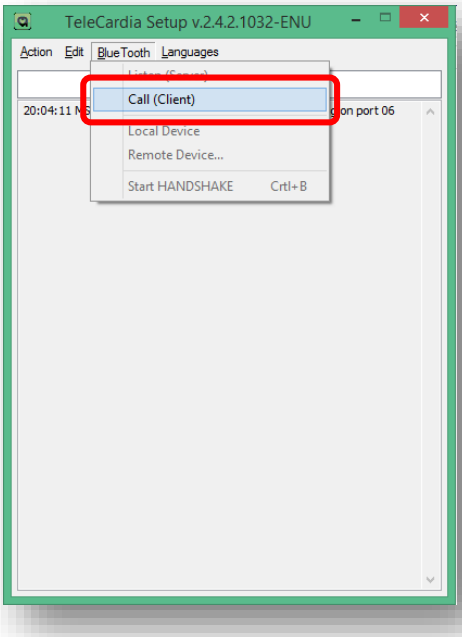

WIDCOMM Bluetooth Software
Installation Complete. Thank you.
Some of the Bluetooth functionality might not be available until the next time you log on.
Finish

Click on “**Finish**”.

Open the “**Program Files**” folder (32-bit processors) or “**Program Files (x86)**” (64-bit processors).



Then, open the “**Parsys**” folder and start the “**TCP.EXE**” software.



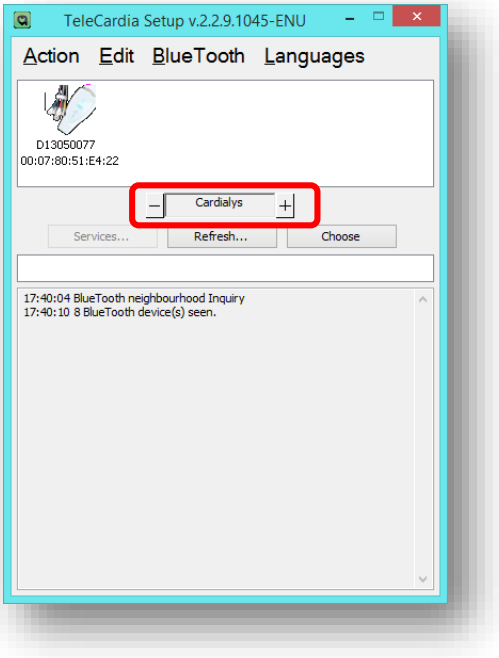
When the software is opened, set the device “**Call (Client)**” mode.

Turn back the Cardialys box

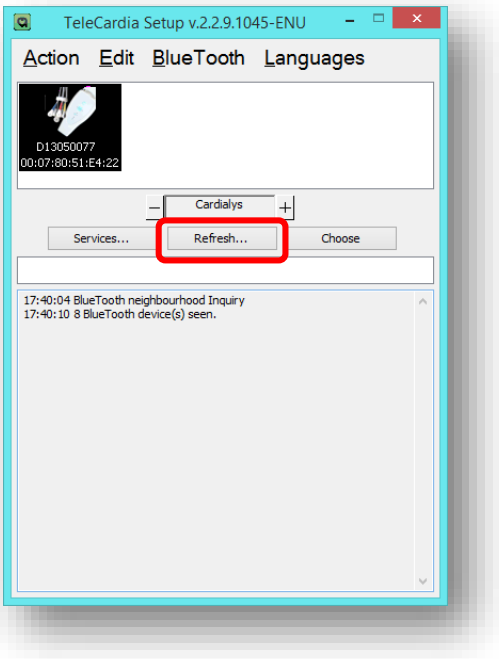
Note the device ID (S/N) on its label:
Number starting with D

Make the connection.

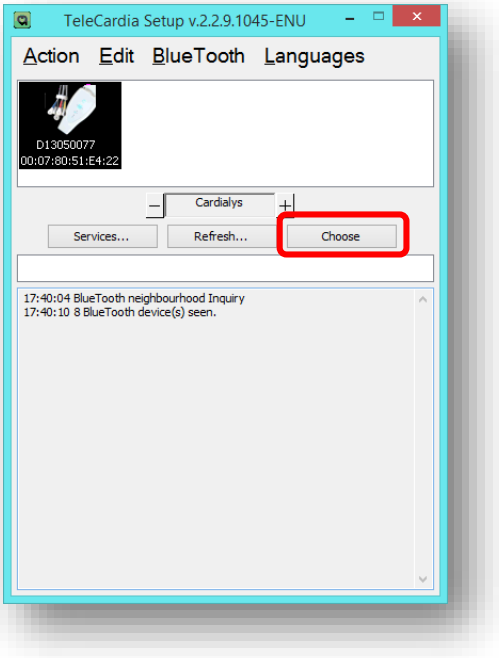
Hold down the **ON/OFF** button until the display of its ID on the screen.



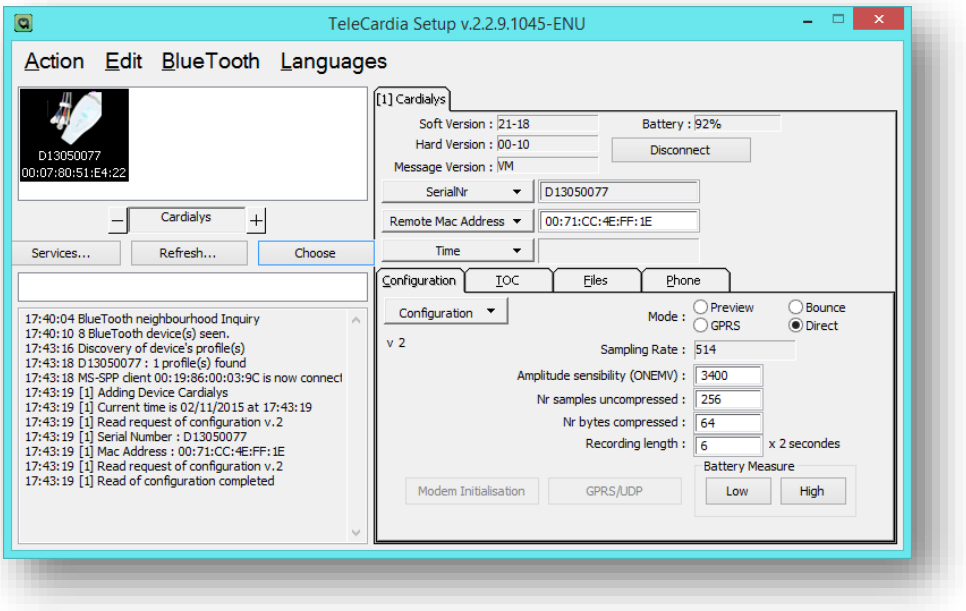
The different connectable Bluetooth devices are recognized by the system.
You can refine the search by type of equipment (Telecardia, Cardialys, etc.).



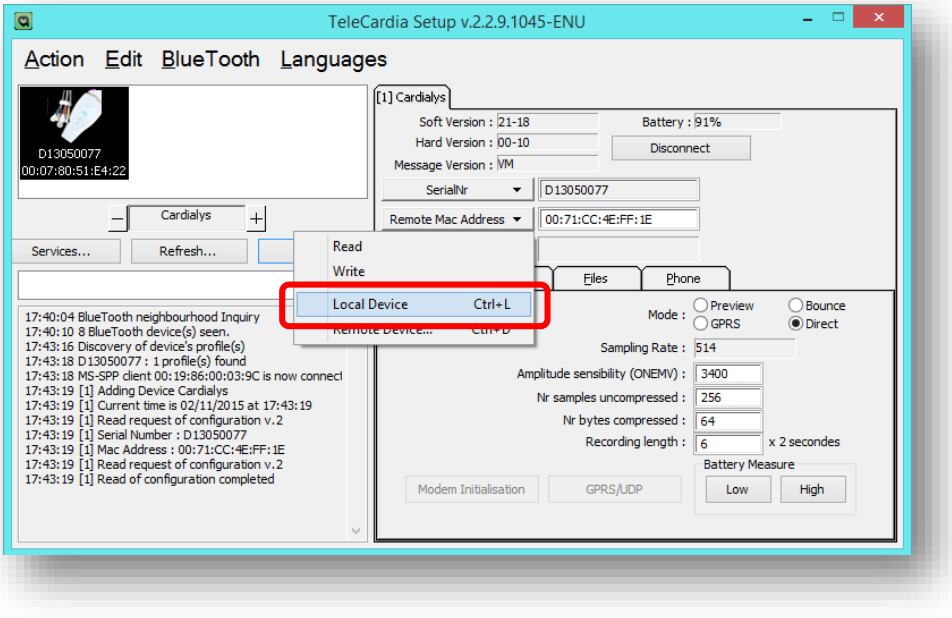
If the search is unsuccessful you can click on "**Refresh…**",
which will start a new search.



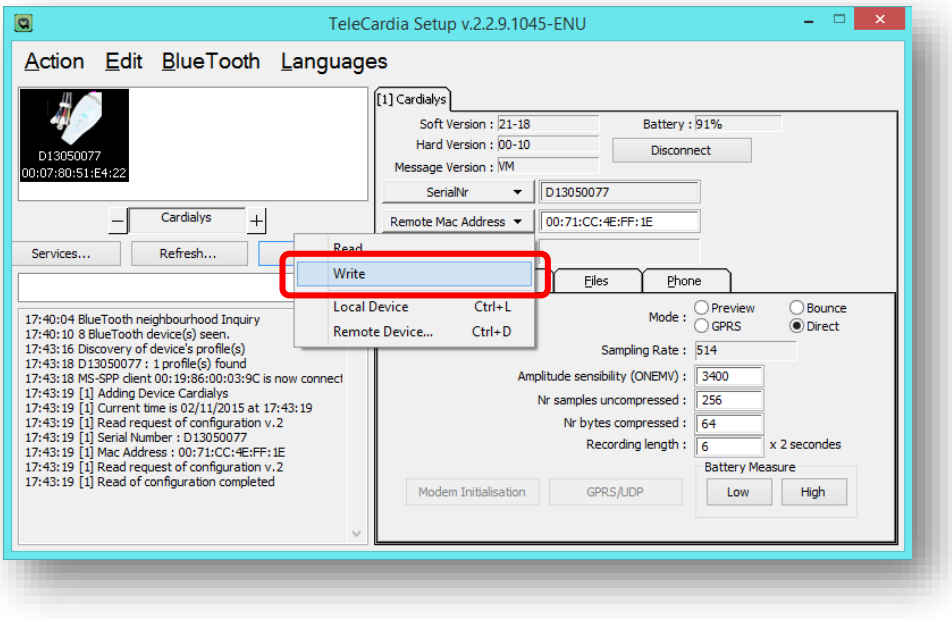
Once the desired device is visible, click its icon (although check the serial number). Then, click on "**Choose**".



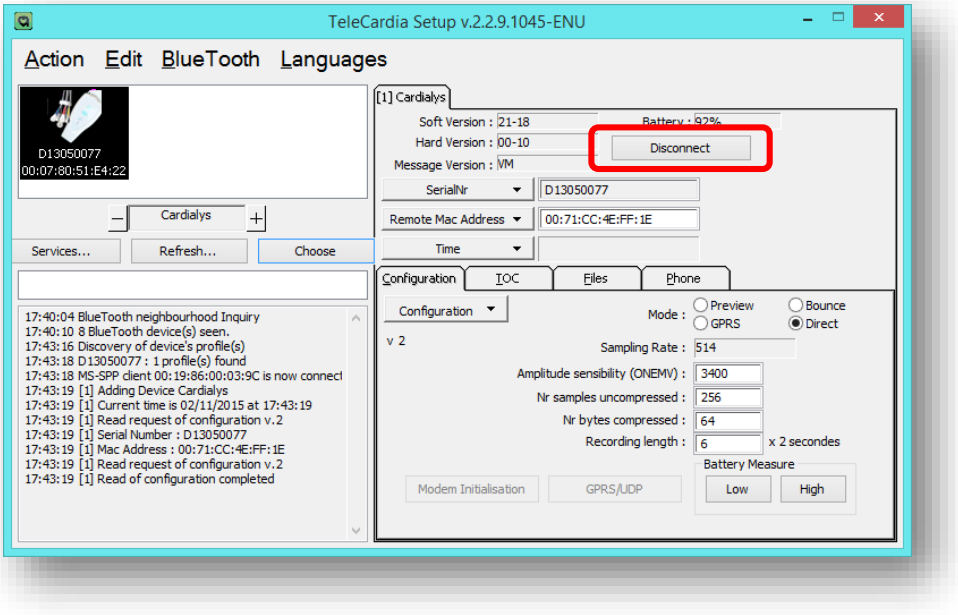
The interface window with the medical device is then visible.



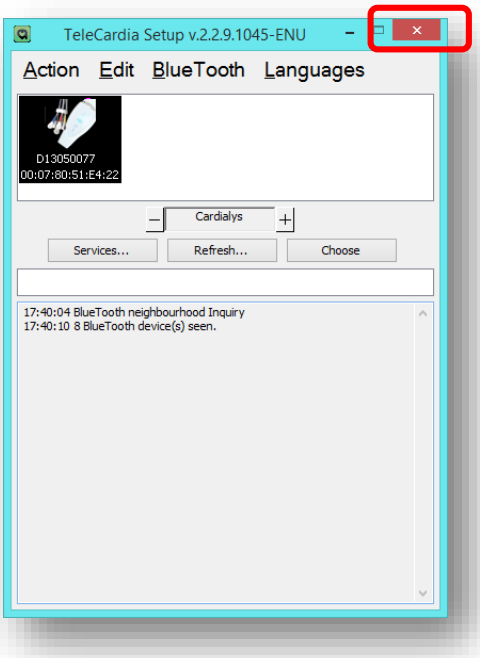
Click on "**Remote Mac Address**".
Then, click on "**Local Device**".
The PC MAC address will be registered.



Click on "**Remote Mac Address**".
Then, click on "**Write**" to save the new MAC address.



Click on "**Disconnect**".



Back to the start window of the "**TCP**" software.
Close the window to exit.

5 Using Telecardialys PC Software

See the User Manual Telecardialys Software - 37-063 V1.0

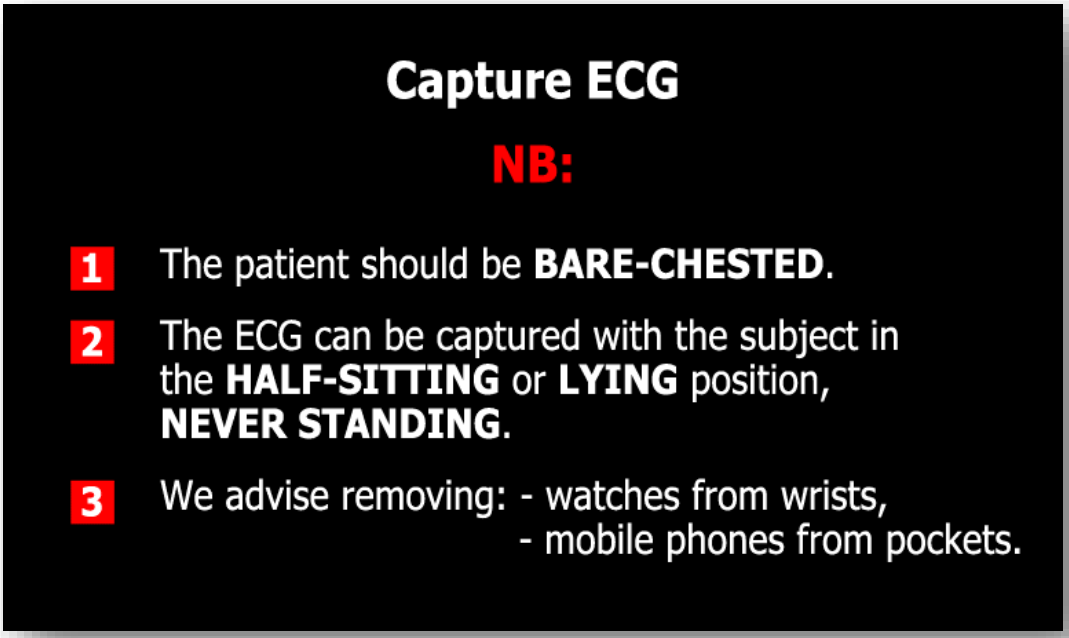
6 ECG capture

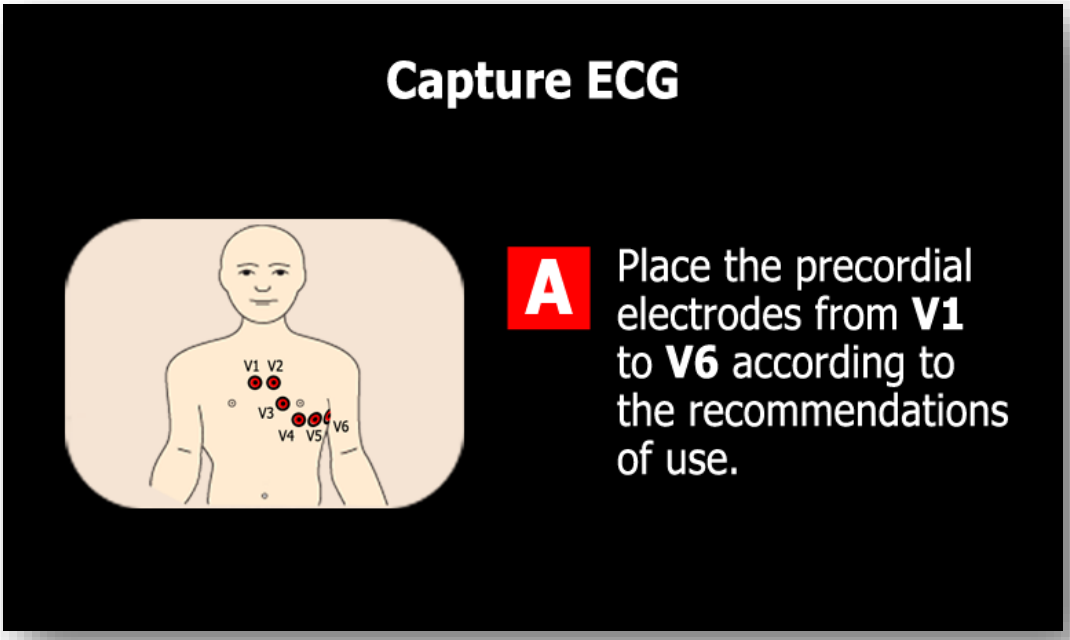
6.1 Cardialys in Direct mode

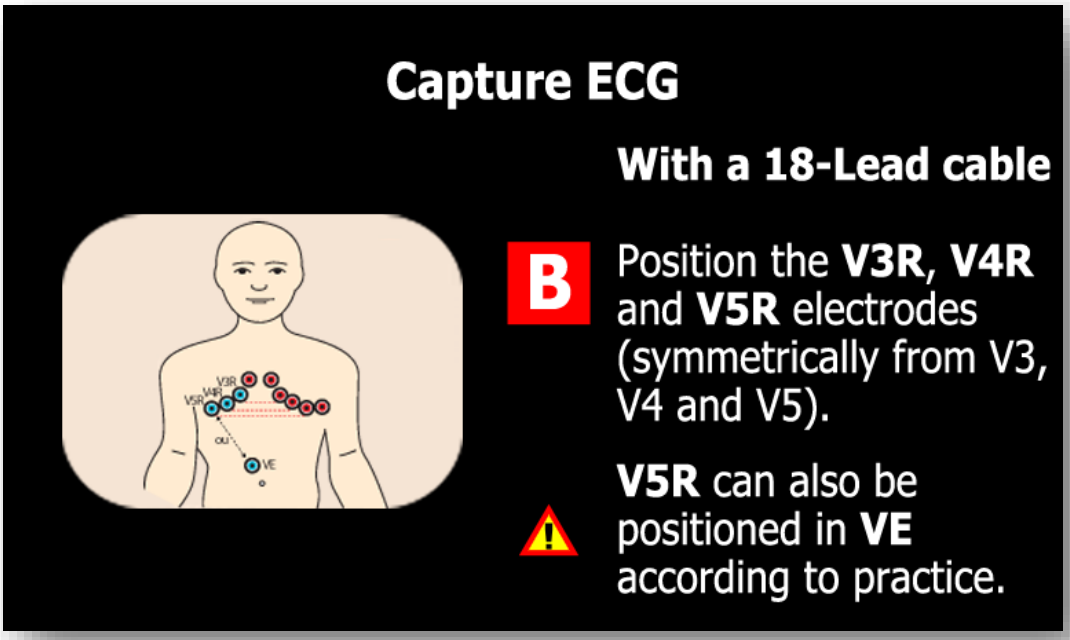
The electrocardiograph (ECG) Cardialys in Direct mode allows the user to capture a simultaneous 12 or 18-lead ECG (depending on options selected).

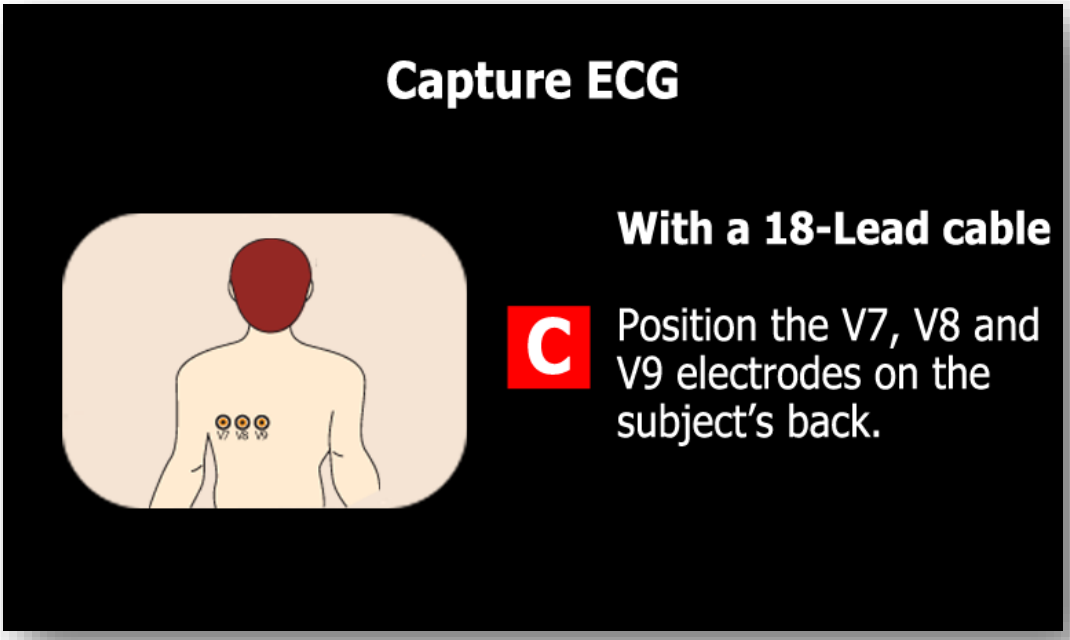
To make an ECG capture, we recommend that:

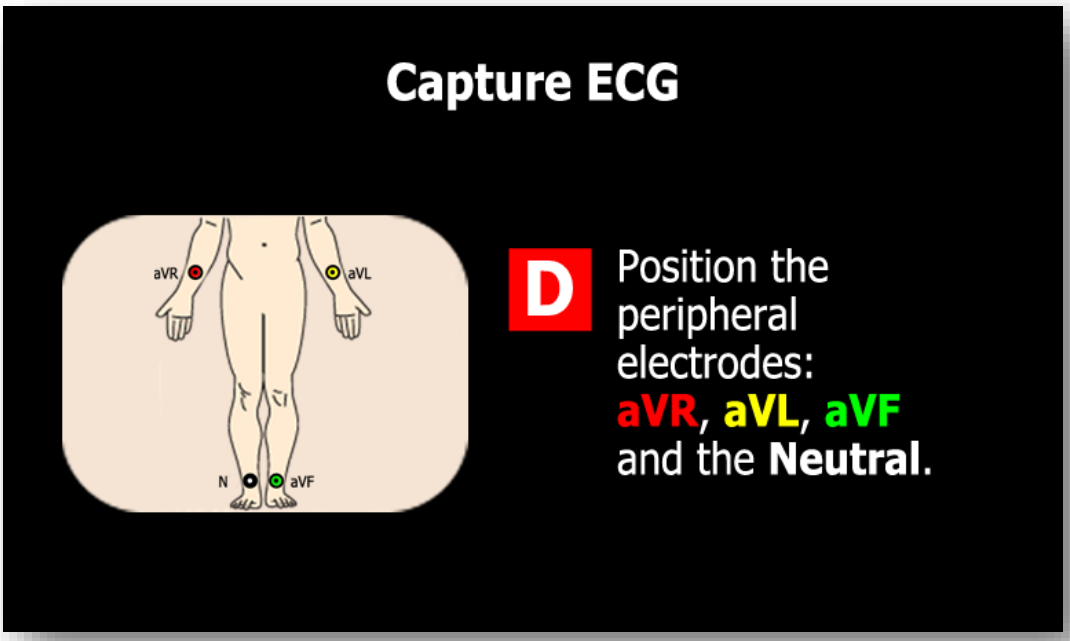
1. Start the capture on the software.
2. Follow the instructions below:

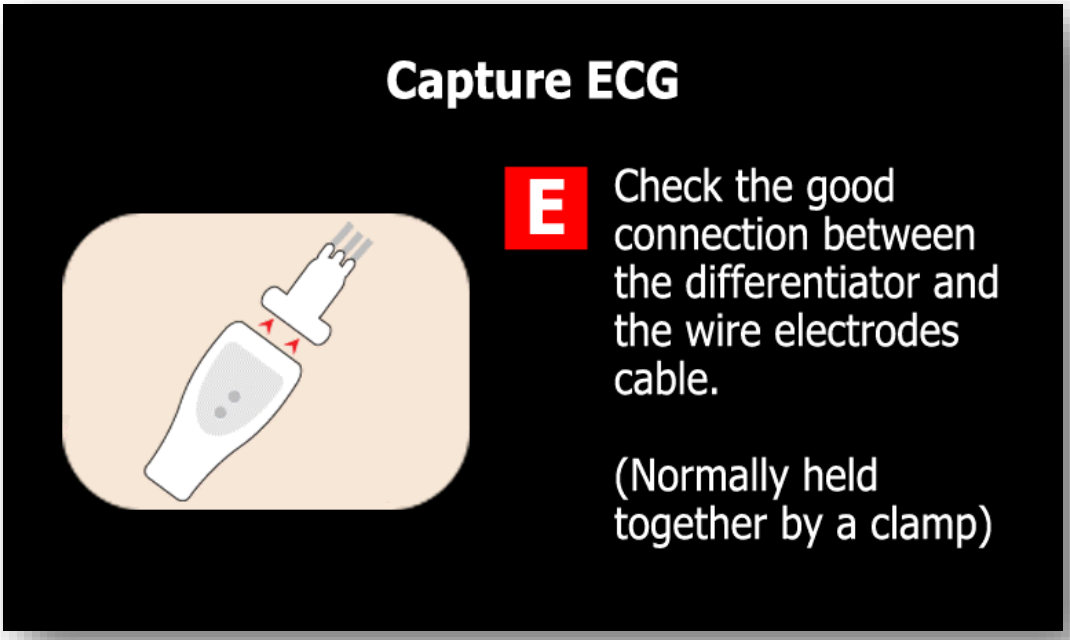

Capture ECG
NB:
1 The patient should be BARE-CHESTED.
2 The ECG can be captured with the subject in the HALF-SITTING or LYING position, NEVER STANDING.
3 We advise removing: - watches from wrists, - mobile phones from pockets.

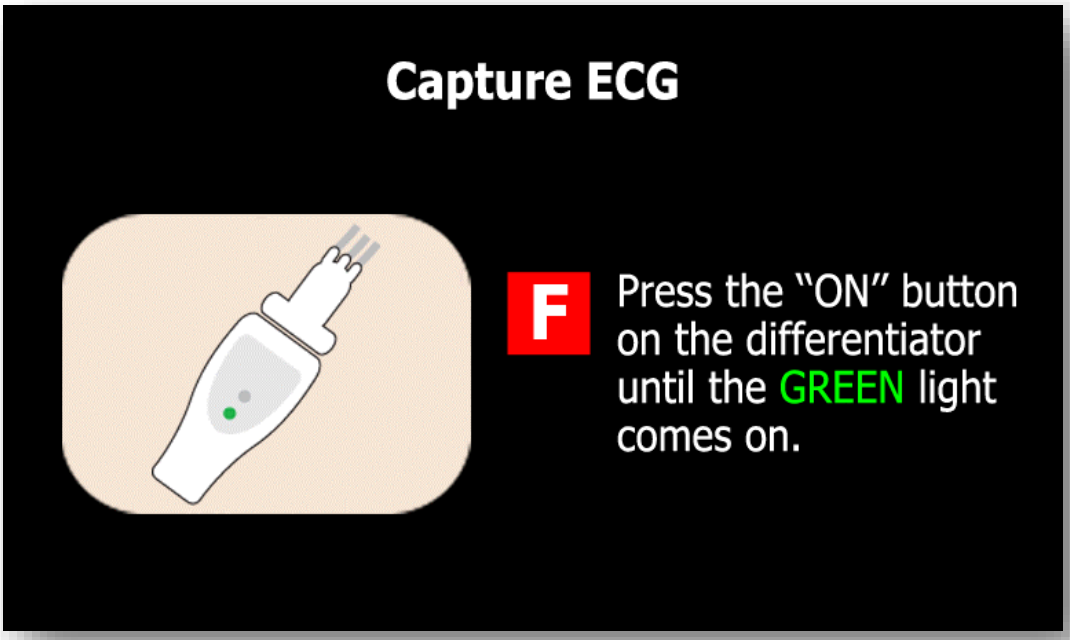

Capture ECG
V1 V2
V3
V4 V5
V6
A
Place the precordial electrodes from V1 to V6 according to the recommendations of use.

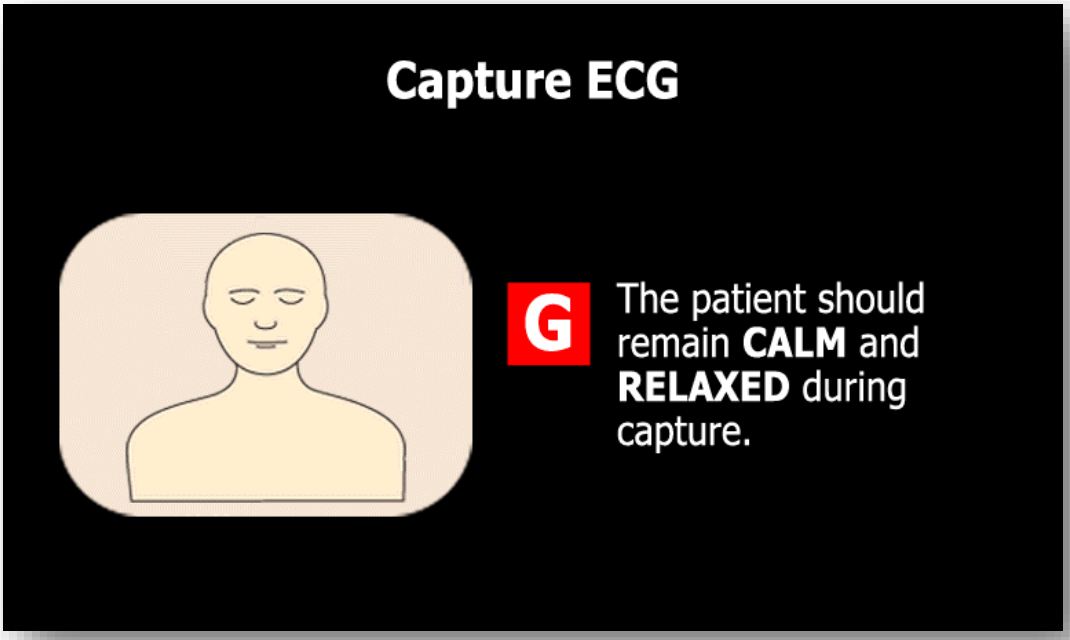

Capture ECG
With a 18-Lead cable
V3R
V4R
V5R
ou
VE
B
Position the V3R, V4R and V5R electrodes (symmetrically from V3, V4 and V5).
V5R can also be positioned in VE according to practice.

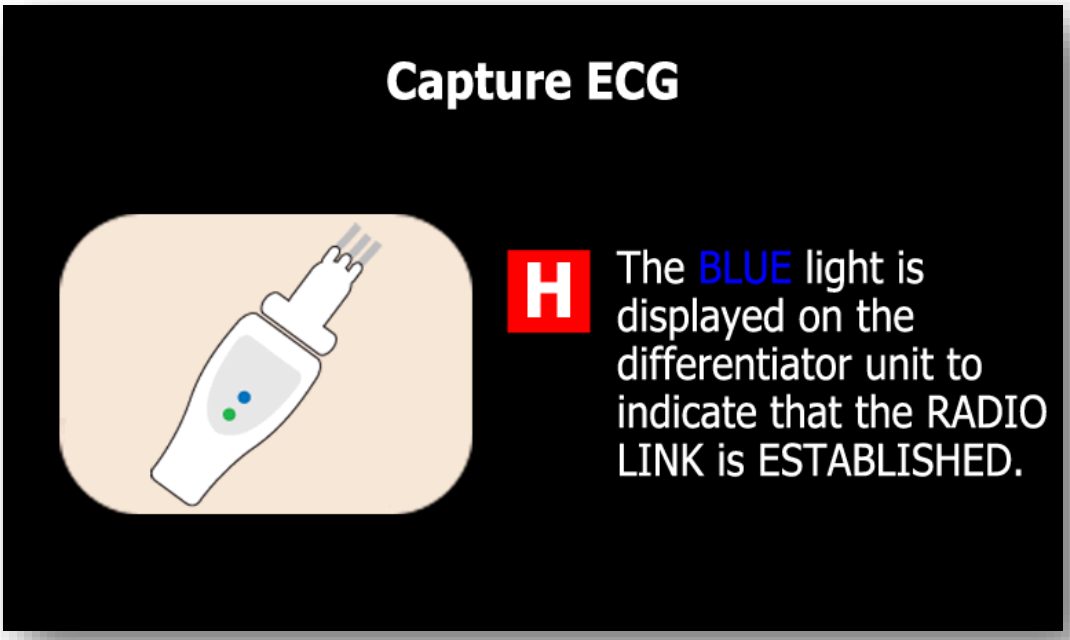

Capture ECG
With a 18-Lead cable
C
Position the V7, V8 and V9 electrodes on the subject's back.

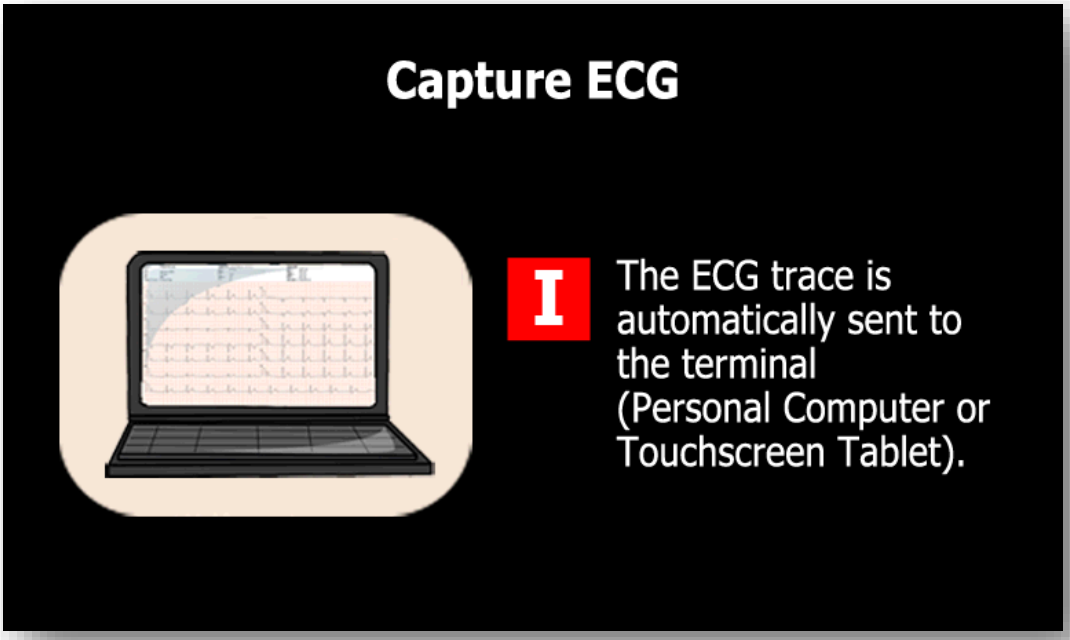

Capture ECG
aVR
aVL
N
aVF
D
Position the peripheral electrodes:
aVR, aVL, aVF
and the Neutral.

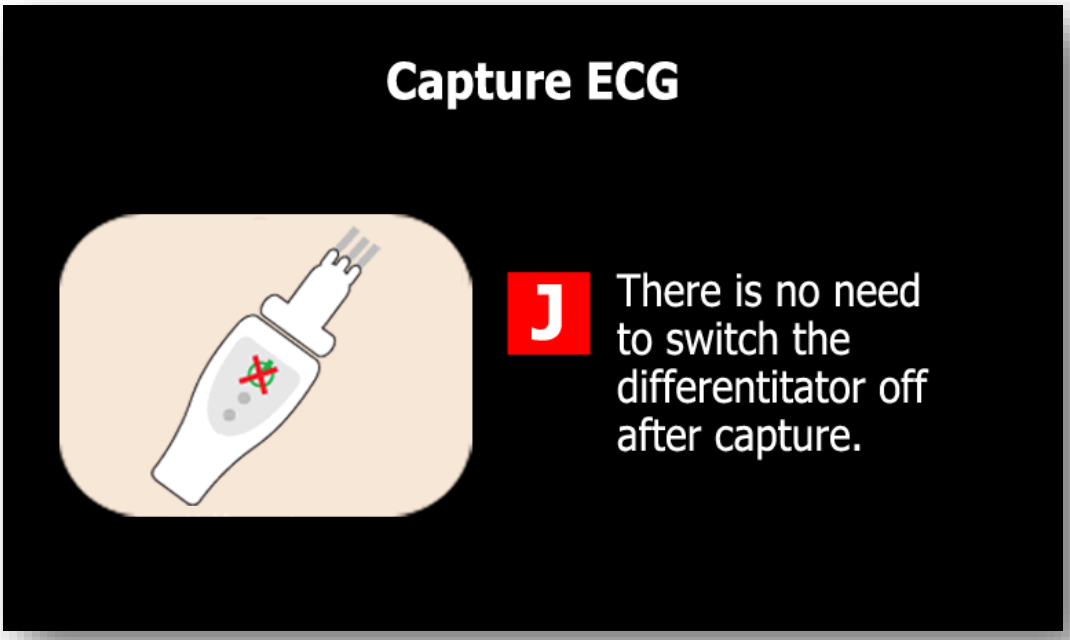

Capture ECG
E
Check the good connection between the differentiator and the wire electrodes cable.
(Normally held together by a clamp)


Capture ECG
F
Press the "ON" button on the differentiator until the GREEN light comes on.


Capture ECG
G
The patient should remain CALM and RELAXED during capture.


Capture ECG
H
The BLUE light is displayed on the differentiator unit to indicate that the RADIO LINK is ESTABLISHED.


Capture ECG
I
The ECG trace is automatically sent to the terminal (Personal Computer or Touchscreen Tablet).

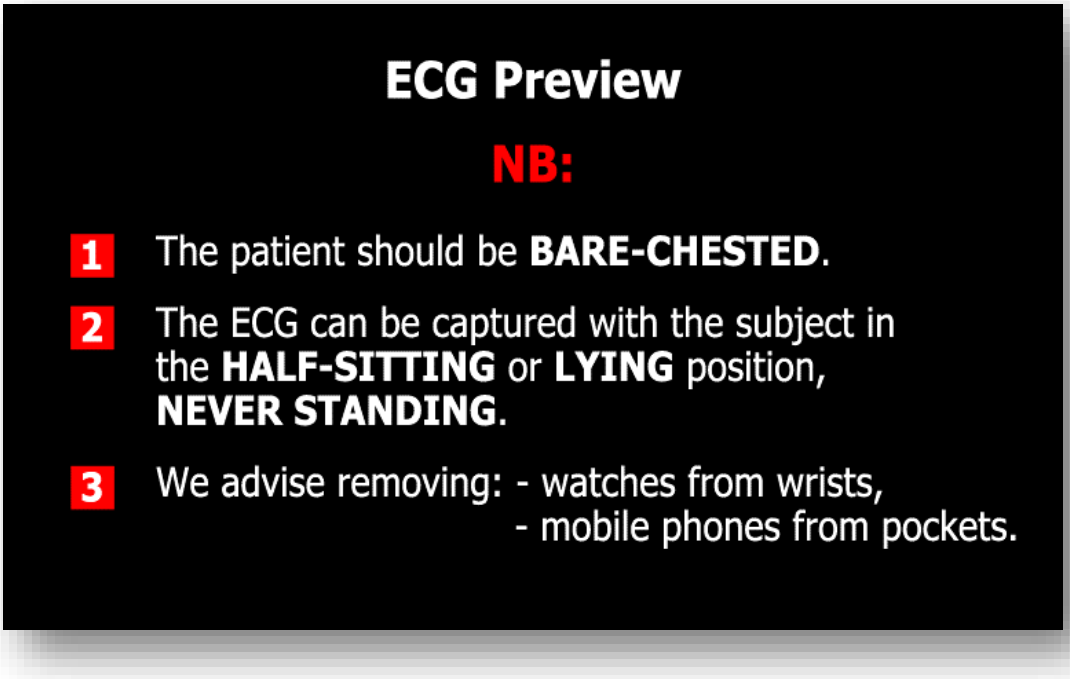

Capture ECG
J
There is no need to switch the differentitator off after capture.

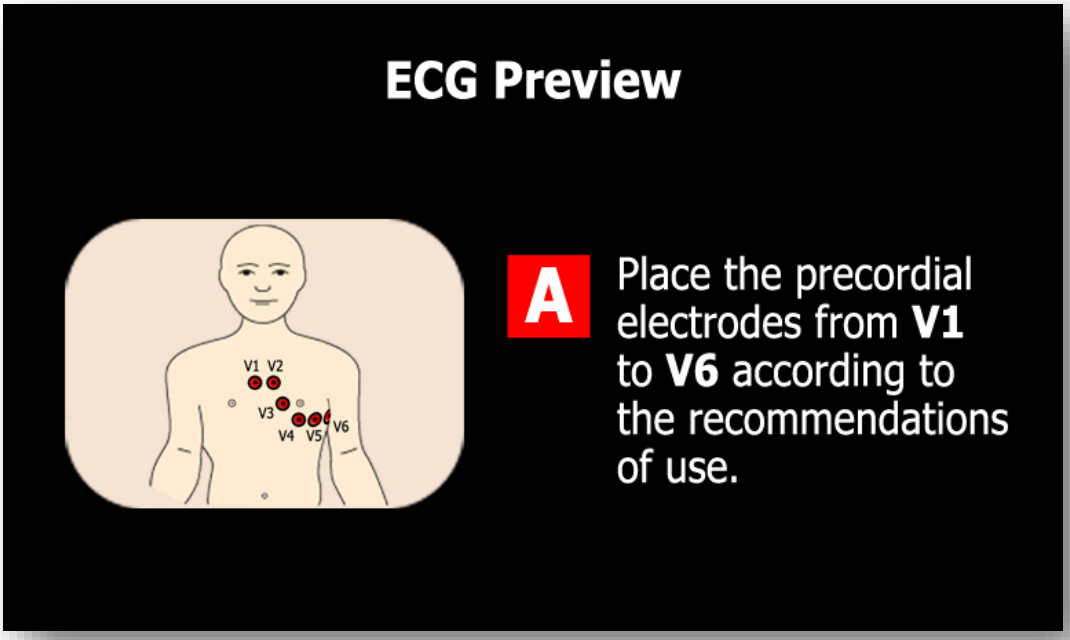
6.2 Cardialys in Preview mode

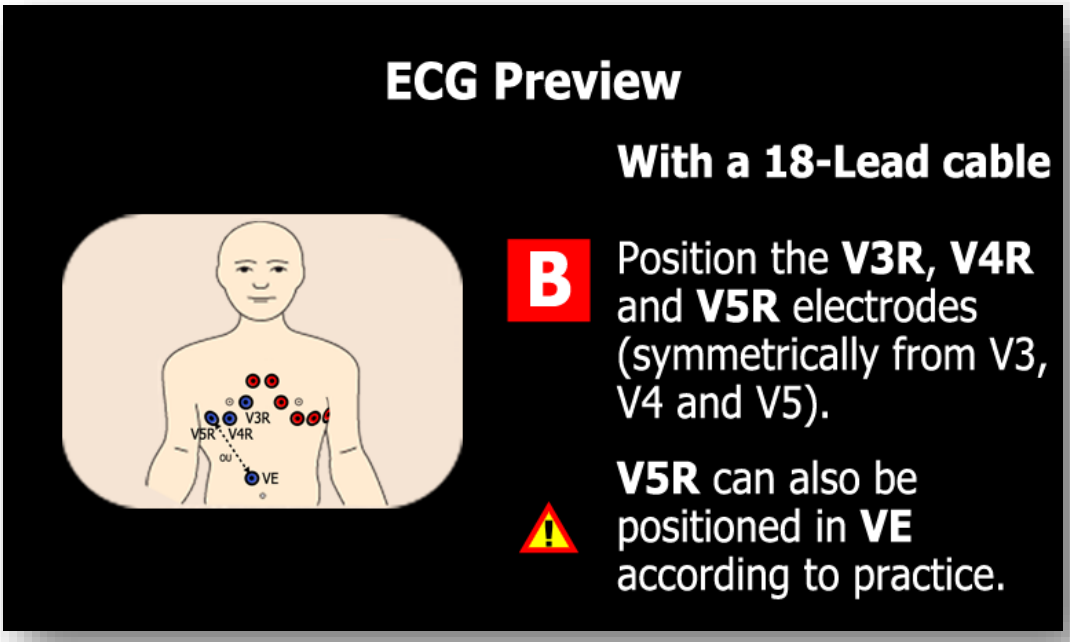
The electrocardiograph (ECG) Cardialys in Preview mode allows the user to preview a simultaneous 12 or 18-lead ECG (depending on options selected), and then to capture an ECG trace.

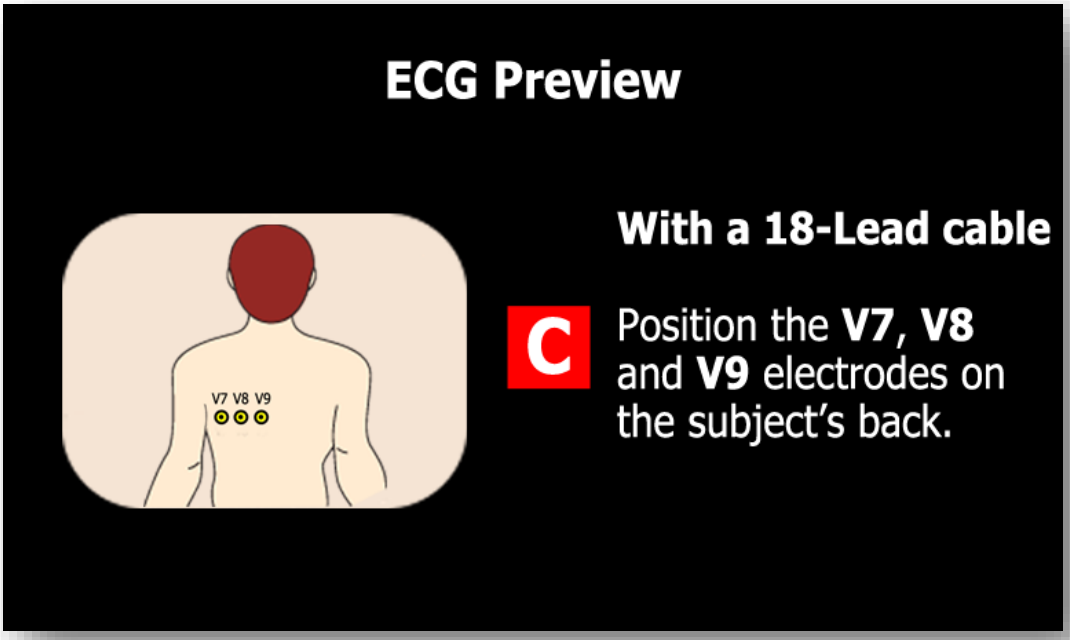
To start the Preview and make an ECG capture, we recommend that:

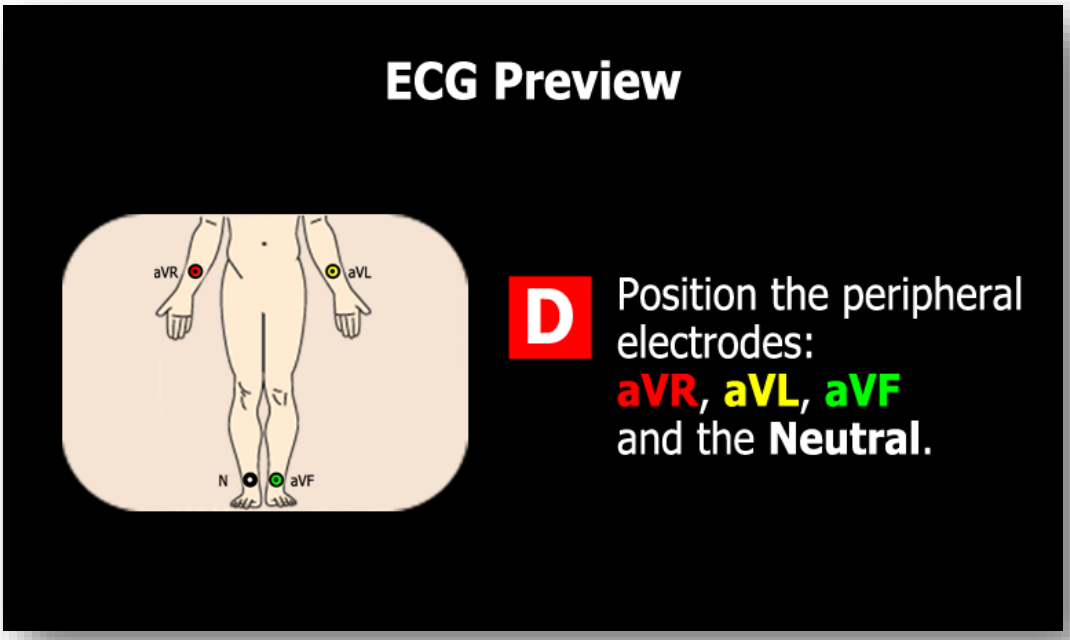
1. Start the Preview on the software.
2. Follow the instructions below:

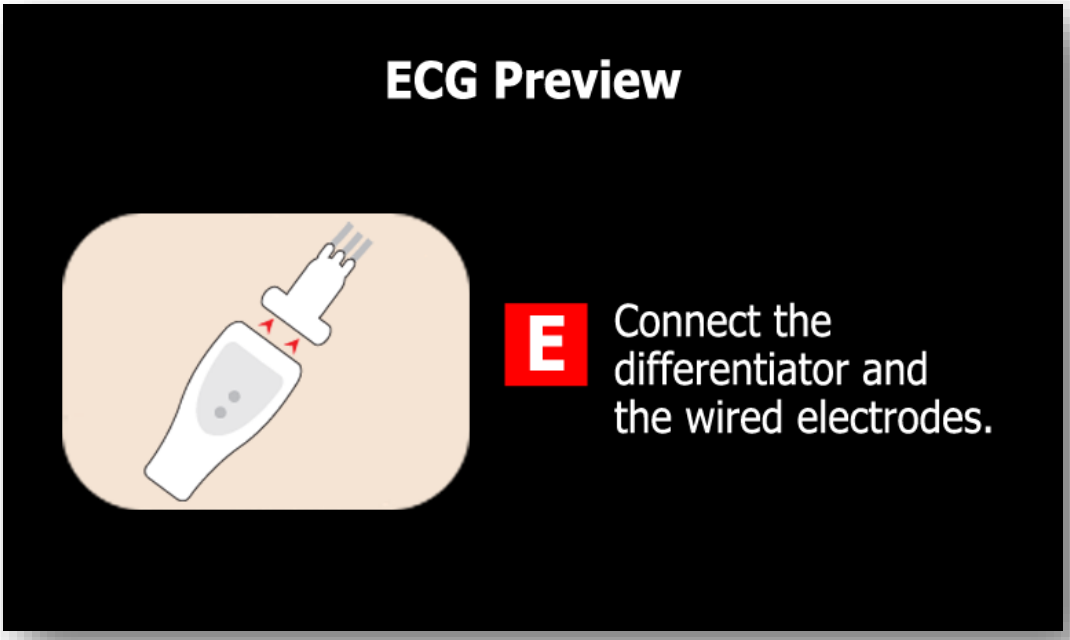

ECG Preview
NB:
1 The patient should be BARE-CHESTED.
2 The ECG can be captured with the subject in the HALF-SITTING or LYING position, NEVER STANDING.
3 We advise removing: - watches from wrists, - mobile phones from pockets.

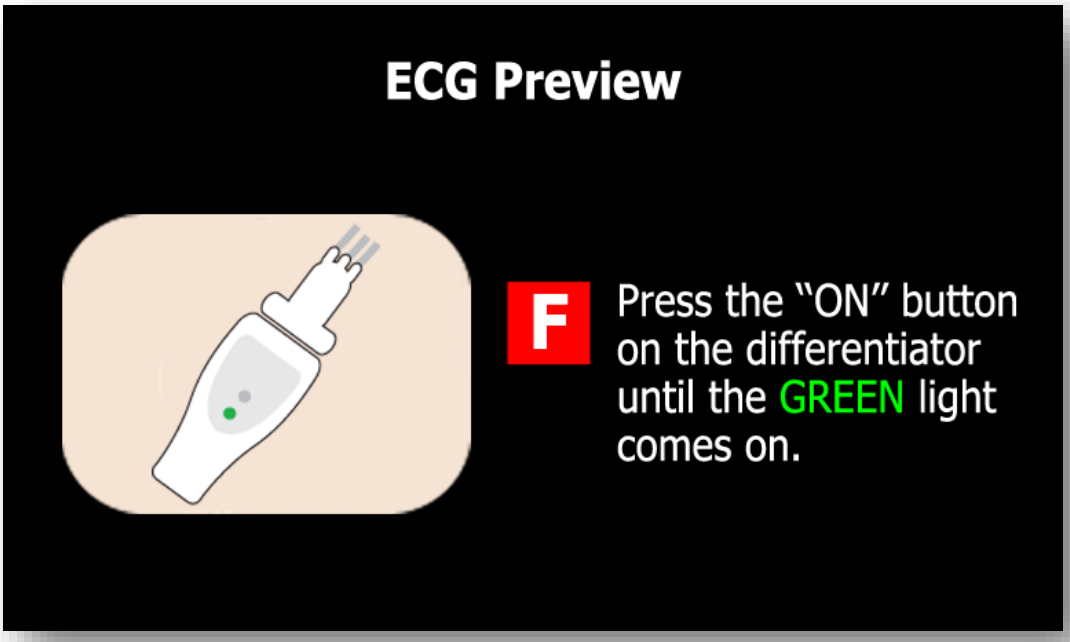

ECG Preview
V1 V2
V3
V4 V5
V6
A
Place the precordial electrodes from V1 to V6 according to the recommendations of use.

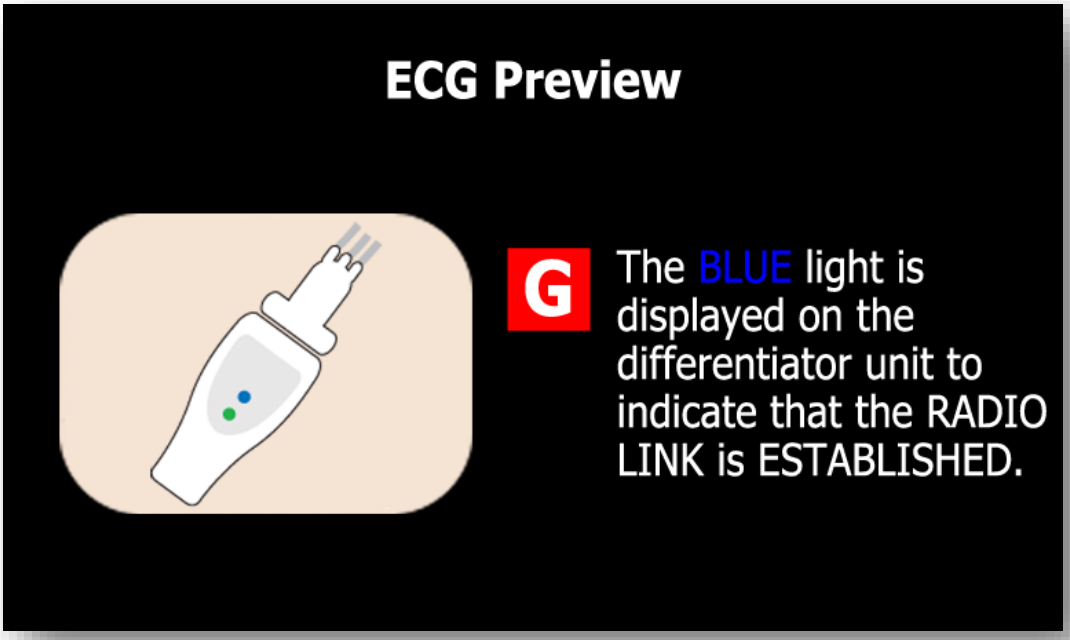

ECG Preview
With a 18-Lead cable
V3R
V5R
V4R
ou
VE
B
Position the V3R, V4R and V5R electrodes (symmetrically from V3, V4 and V5).
V5R can also be positioned in VE according to practice.

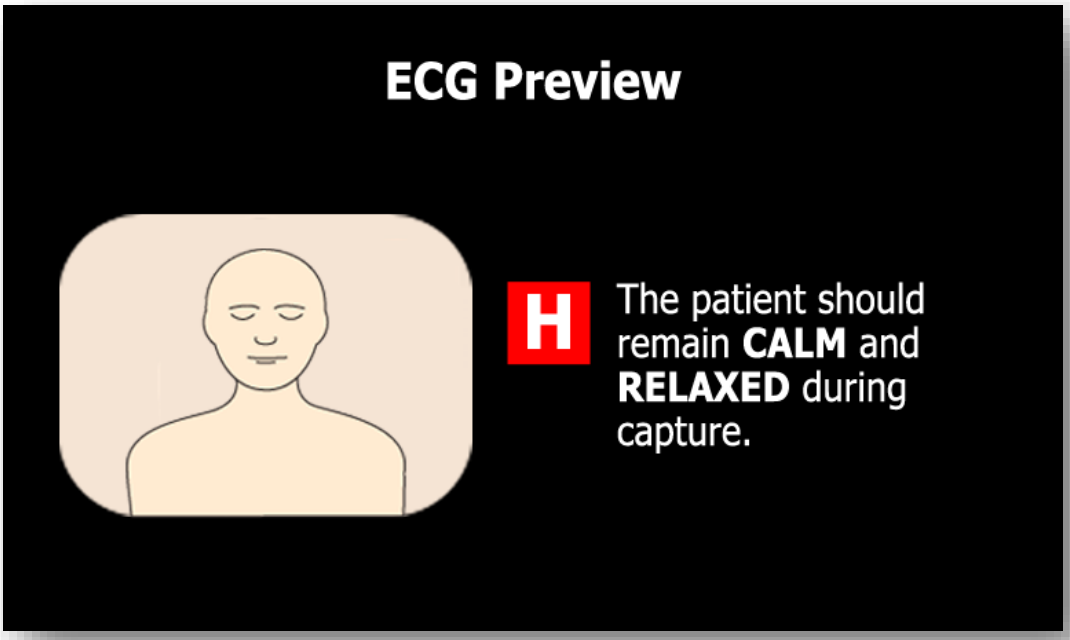

ECG Preview
V7 V8 V9
With a 18-Lead cable
C
Position the V7, V8 and V9 electrodes on the subject's back.

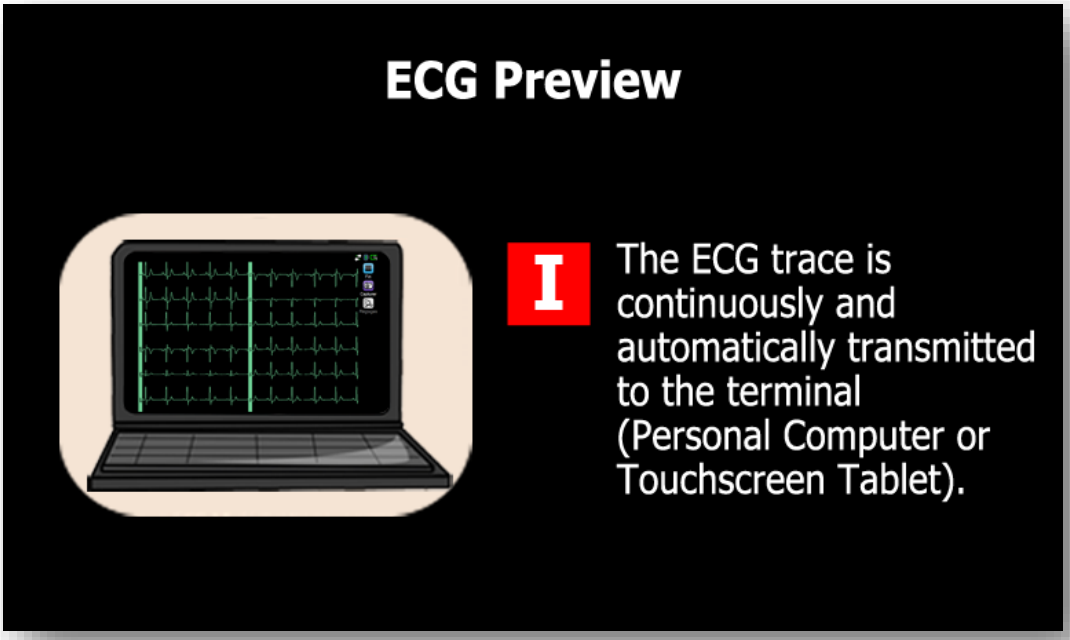

ECG Preview
aVR
aVL
N
aVF
D
Position the peripheral electrodes:
aVR, aVL, aVF
and the Neutral.

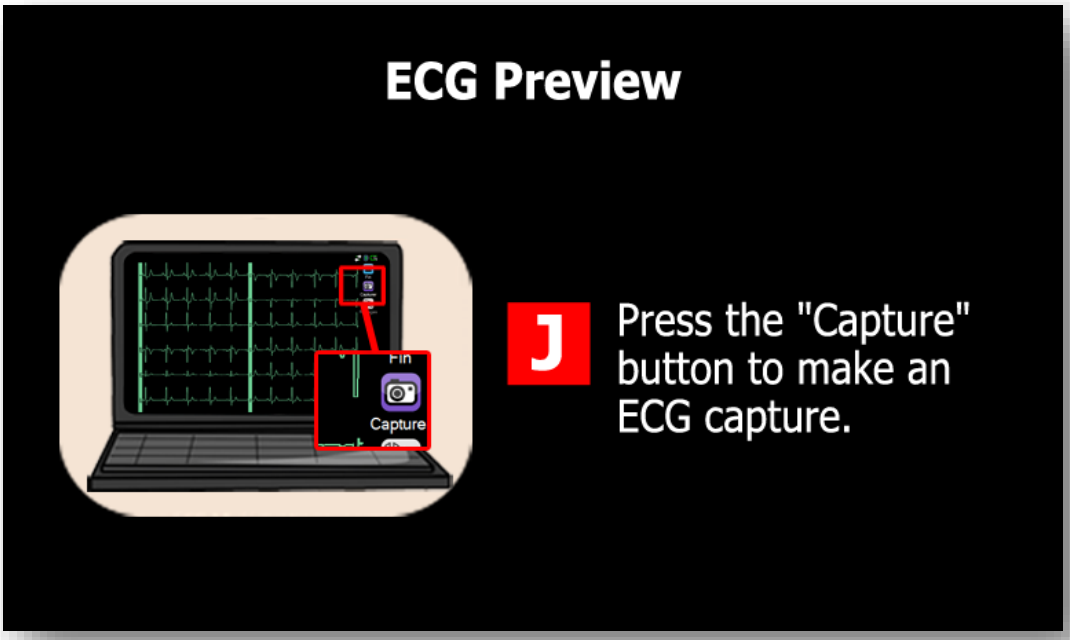

ECG Preview
E
Connect the differentiator and the wired electrodes.

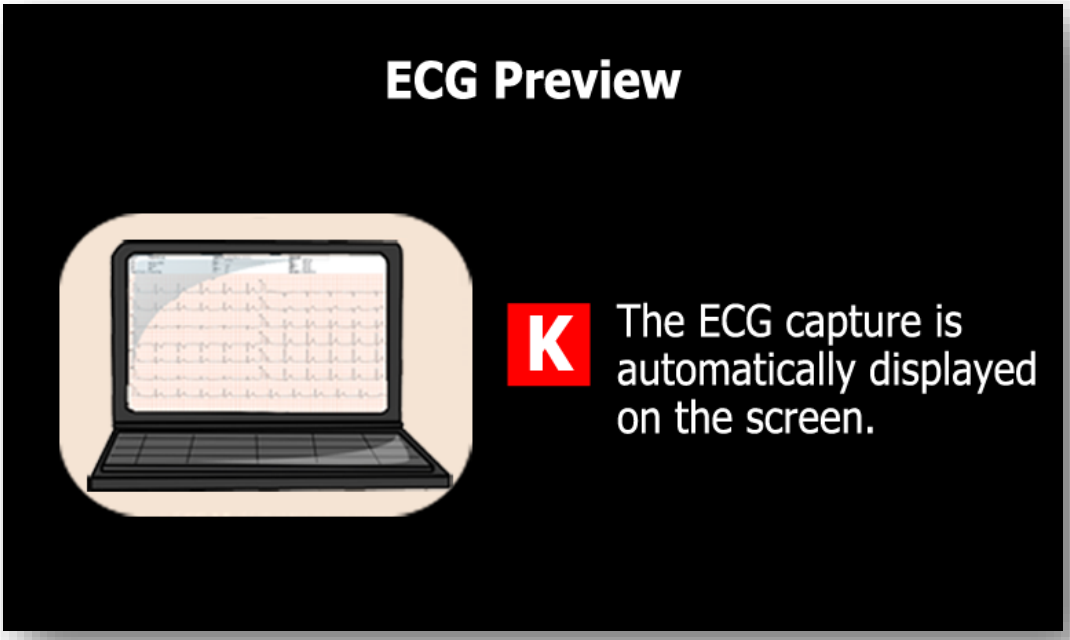

ECG Preview
F
Press the "ON" button on the differentiator until the GREEN light comes on.

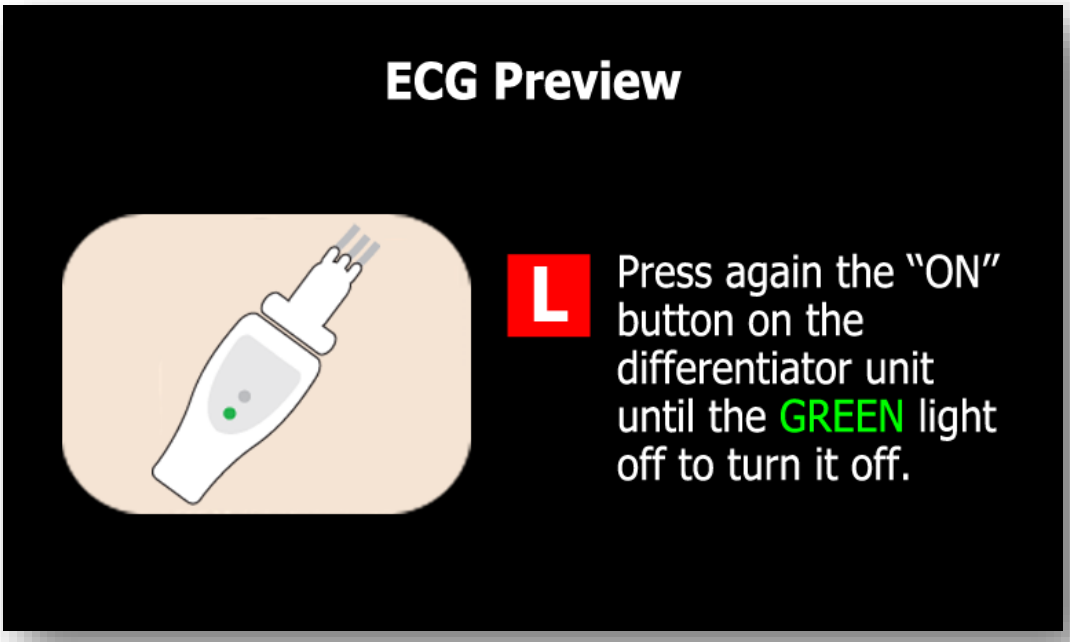

ECG Preview
G
The BLUE light is displayed on the differentiator unit to indicate that the RADIO LINK is ESTABLISHED.


ECG Preview
H
The patient should remain CALM and RELAXED during capture.


ECG Preview
I
The ECG trace is continuously and automatically transmitted to the terminal (Personal Computer or Touchscreen Tablet).


ECG Preview
Capture
J
Press the "Capture" button to make an ECG capture.


ECG Preview
K
The ECG capture is automatically displayed on the screen.


ECG Preview
L
Press again the "ON" button on the differentiator unit until the GREEN light off to turn it off.

7 Updating the PC software / device firmware

We shall contact you periodically by e-mail concerning download of updated software / firmware versions.

The updates are performed during maintenance.

8 Electromagnetic emissions

Table 1: Directives and MANUFACTURER'S statement – ELECTROMAGNETIC EMISSIONS

For all DEVICES and EM SYSTEMS

Directives and manufacturer's statement – electromagnetic emissions		
The device is made to be used in the electromagnetic environment specified below. The client or user of the device must ensure that the device is used in such environment.		
Emission trials	**Conformity**	**Electromagnetic environment – directives**
RF Emissions CISPR 11	Group 1	The device uses RF energy only through his internal functions. As a consequence, its RF emissions are very weak and are not likely to cause interferences in a nearby electronic device.
RF Emissions CISPR 11	Class B	The charging power box (catalogue product) must solely be used with the device in sleep mode, disconnected from the patient.
Harmonic Emissions CEI 61000-3-2	Non applicable	
Pulse fluctuations/ Flicker CEI 61000-3-3	Non applicable	

Table 2 – Directives and MANUFACTURER'S statement – electromagnetic IMMUNITY

For all DEVICES and EM SYSTEMS

Directives and manufacturer's statement – electromagnetic immunity			
The device is made to be used in the electromagnetic environment specified below. The client or user of the device must ensure that the device is used in such environment.			
Immunity trials	**Trial level CEI 60601**	**Conformity level**	**Electromagnetic environment – directives**
Electrostatic shocks (ES) CEI 61000-4-2	+/- 6 kV in contact +/- 8 kV in the air	Conforms	Floors must be made of wood, concrete or ceramics. If the floors are topped with synthetic materials, it is important that the relative humidity remains at 30% at least.
Magnetic field at the rate of the electric network (50/60 Hz) CEI 61000-4-8	3 A/m	Conforms	Magnetic fields at the rate of the electric network must have the distinctive levels of a representative place located in a commercial or hospital environment.

Table 3 – Directives and MANUFACTURER'S statement – electromagnetic IMMUNITY

For all DEVICES and EM SYSTEMS

Directives and manufacturer's statement – electromagnetic emissions			
The device is made to be used in the electromagnetic environment specified below. The client or user of the device must ensure that the device is used in such environment.			
Emission trials	**Trial level CEI 60601**	**Conformity level**	**Electromagnetic environment – directives**
RF conducted disturbances CEI 61000-4-6	3 Veff from 150kHz to 80MHz	3 Veff	The portable and mobile RF communicating devices should be not used nearer of any part of the medical devices, including cables, than the recommended separation distance, calculated from the transmitter frequency applicable equation. **Recommended separation distance** **d= 1,2√P** **d= 1,2√P** from 80MHz to 800MHz **d= 2,3√P** from 800MHz to 2,5GHz where **P** is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m) of separation. It should that field strengths from fixed RF transmitters, as determined by an electromagnetic survey on site [a], should be less than the compliance level in each frequency range [b]. Interferences may occur in the vicinity of equipment marked with the following symbol:
RF radiated disturbances CEI 61000-4-3	3 V/m from 80 to 2,5GHz	3 V/m	
NOTE 1: to 80MHz and to 800MHz, the higher d range frequency applies. **NOTE 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM / FM radio and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, it should be considered to proceed to an electromagnetic survey on site. If the measured field strength in the location where the medical device is used, exceeds the applicable RF compliance level above, it is necessary to observe the behavior of the medical device, to check that the operation is normal. If abnormal performances are observed, additional measures may be necessary, such as reorienting or repositioning of the medical device on its operation site.

[b] In the frequency range of 150kHz to 80MHz, it is appropriate that the field strengths are smaller than 3 V/m.

Recommended separation distances between portable and mobile RF communicating devices and the medical device.

The medical device is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The customer or the user of the device can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communicating device (transmitter), and the medical device, as recommended below, according to the maximum power emission of the communication device.

Transmitter maximum assigned power output (W)	**Separation distance according to the transmitter frequency (m)**		
	from 150kHz to 80MHz **d= 1,2√P**	from 150kHz to 80MHz **d= 1,2√P**	from 150kHz to 80MHz **d= 2,3√P**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters whose maximum assigned transmission power is not given above, the recommended separation distance **d** in meters (m) can be estimated by using the transmitter frequency applicable equation, where **P** is the characteristic of the transmitter maximum transmission power in watts (W) according to its manufacturer.

NOTE 1: to 80MHz and to 800MHz, the higher d range frequency applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9 Technical features

9.1 Individual recording characteristics

- ECG traces, 2-second pitch adjustable length in 'TéléCardia' mode, of ordinary length, 1-second pitch in PC direct reading (monitoring) mode.
- Number of leads for selection prior to capture (12/18).
- ECG timestamping.
- Patient identification.
- Identification of the device and the embedded Software version used to make the recording

9.2 General features

- ***Type***: class 2A, ECG 12/18 lead device for temporary use
- ***Space requirements***: 130x70x25mm (not including patient cable)
- ***Weight***: 110 g (patient cable 310 g in the 18-lead version).
- ***Plastic case*** ABS, 26 arbour finish
- ***Patient cable interface***: 25 pin SUB-D High mechanical endurance.
- ***Power supply***: Lithium Polymer 3.7V/750mAh, rechargeable battery power supply, replacement part available from the PARSYS Telemedicine After-Sales Service.
- ***Battery life cycle:*** 3 years life cycle
- ***Operating temperature range***: +10C°/+35°C
- ***Storage temperature range***: -10°C/+60°C
- ***Charging*** : by the charging contacts at the base of the device, using a special charger
- ***Man-Machine Interface***:
  - On/Off push-button on the front,
  - blue LED for Bluetooth link,
  - green/orange/red LED indicating 'power on' and battery status (respectively >100%/ 20%> bat > 5%/ < 5%). Automatic shut down after one minute of inactivity.
- ***BF type applied part protected against defibrillation shocks***.
- ***Protection against water ingression – ordinary.***

9.3 Electrical specifications

- Supply voltage: 2.5v to 4.3v DC
- Consumption: 170mA @ 3.8v type during capture, 200 mA @3.8v typ. during connection
- 16 bit scanning
- 500 Hz sampling frequency
- 18 simultaneous leads
- Bandwidth: 0.05 Hz -> 40 Hz
- Voltage input range: +/- 5mV
- Input impedance: 10MΩ
- Protected against defibrillation shocks
- SPP profile, class 1, 2.0 EDR Bluetooth radio link

10 Maintenance

10.1 Cleaning / Disinfection

The machine can be cleaned and disinfected by wiping the plastic unit with cotton wool or a wipe soaked in a product such as STERANIOS or equivalent (2% glutaraldehyde solution).

10.2 Procedure in the event that the instrument is dropped or falls

Mechanical damage to the instrument necessarily implies discontinuation of use of the machine and return to the PARSYS Telemedicine After-Sales Service.

10.3 Reset procedure

If, when using the instrument, it blocks for more than 1 min:

- use the reset cable or a metallic object (paper clip, pair of scissors or wire), to connect the 2 charging contacts under Cardialys and hold in contact for 1 second,
- place the equipment back on the charger and wait for the Charger indicator to come on,
- connect in settings mode to update the internal real-time clock,
- stop then restart the instrument.

10.4 Metrological checks

The instrument shall undergo metrological checks after 1 year maximum, and these must be carried out by the PARSYS Telemedicine technical department, it alone being able to guarantee maintenance of the instrument's metrological performance throughout its life cycle.

10.5 Processing of out-of-use equipment

In accordance with directive 2002/96/EC relating to waste electrical and electronic equipment (WEEE), the device must not be disposed of with household waste and must be taken to a specialist waste collection centre.

11 Users' Training

Users of the Cardialys ECG must:

- have kind of medical knowledge of physician, nurse or first aider,
- hold the associate degree,
- have been trained on this medical device.

12 Fault or failure

12.1 The Cardialys ECG does not send any trace

After capturing the ECG, no trace is received by paired PC: the Bluetooth® connection is most certainly lost.

We therefore advise you:
- **NEVER ATTEMPT any direct manipulation on the PC;**
- **Contact the PARSYS Telemedicine After-Sales Service.**

12.2 The ECG is subject to interference

Check that the capture protocol has been followed, in particular:
- the correct position of the electrodes,
- absence of contact between the electrodes and any objects likely to cause electrical interference,
- absence of mobile phones nearby.

The patient and operator must be as relaxed as possible in order to avoid any tense movements when capturing the ECG.

12.3 The Cardialys ECG remains frozen when in operation

If the machine **blocks when in operation for more than 1 minute**:
- use the reset cable or a metallic object (paper clip, pair of scissors or wire), to connect the charging contacts under Cardialys and hold in contact for 1 second,
- place the equipment back on the charger and wait for the Charger indicator to come on,
- connect in settings mode to update the internal real-time clock,
- stop then restart the instrument.

12.4 The Cardialys ECG is not charging

Check that the charging protocol has been followed, in particular:
- that the Cardialys is in the correct position on the charger,
- that the wired cable has been disconnected during charging (to unburden Cardialys and to ensure proper contact with the metal contacts on the base),
- that the red LED on the base is on during charging,
- that the base is correctly plugged into the mains.

Should you note a low battery level after 1 hour's charging, please contact the PARSYS Telemedicine After-Sales Service.

13 PARSYS Telemedicine Warranty and After-Sales Service

The Customer agrees to comply with the Warranty Conditions listed on the Warranty Certificate accompanying the Equipment.

The Equipment is supplied with a one-year (1) warranty during which period the Customer will be able to exchange Equipment found to have a latent defect and subject to the Customer having informed PARSYS Telemedicine thereof in writing and in detail.

In the event of a functional fault or failure of the Equipment, the Customer may contact PARSYS Telemedicine:

- by sending an e-mail to **support@parsys.com**,
- or by calling the PARSYS Telemedicine After-Sales Service:
  - Monday to Friday, 10 a.m. - 12.30 p.m. and 2 p.m. - 6p.m., except for bank holidays,
  - at **+33 (0)1 60 31 51 71**
- or by sending a letter by recorded delivery with acknowledgement of receipt to:

PARSYS Telemedicine - After-Sales Service
5-7, avenue de Paris 94300 Vincennes - FRANCE

The PARSYS Telemedicine After-Sales Service identifies the nature of the fault or failure of the Equipment before carrying out any repairs or replacing the defective Equipment.

Beyond the warranty period, the Customer has the possibility of subscribing to a maintenance contract with the PARSYS Telemedicine sales department.